

Exhibit 2

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1 UNITED STATES DISTRICT COURT

2 DISTRICT OF NEW JERSEY

3 Case No. MDL No. 16-2738 (MAS) (RLS)

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5 IN RE: JOHNSON & JOHNSON

6 TALCUM POWDER PRODUCTS

7 MARKETING, SALES PRACTICES,

8 AND PRODUCTS LIABILITY

9 LITIGATION

10 _____ /

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14 The Deposition of ANALISA DIFEO, PhD,

15 Taken at 120 W. Huron Street,

16 Ann Arbor, Michigan,

17 Commencing at 9:16 a.m.,

18 Friday, June 28, 2024

19 Before Laura J. Steenbergh, CSR-3707, RPR, CRR, RMR

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7 (973) 549-7000	7
8 susan.sharko@faegredrinker.com	8 INDEX TO EXHIBITS
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1 Ann Arbor, Michigan 2 Friday, June 28, 2024 3 About 9:16 a.m. 4 MS. THOMPSON: Morgan Thompson, I'm with 5 Beasley Allen, and I represent the plaintiffs in the 6 MDL. 7 MS. O'DELL: Leigh O'Dell, Beasley Allen, on 8 behalf of plaintiffs. 9 MS. PARFITT: Michelle Parfitt, Ashcraft & 10 Gerel, on behalf of the plaintiffs. 11 MS. EMMEL: Jennifer Emmel, Beasley Allen, on 12 behalf of the plaintiffs. 13 MS. PITTARD: Leanna Pittard, with Beasley 14 Allen, on behalf of the plaintiffs. 15 MS. SHARKO: Susan Sharko, Faegre Drinker, for 16 the J&J defendants. 17 MR. FRIEDMAN: Eric Friedman, also with Faegre 18 Drinker, for the J&J defendants. 19 MS. HARRIS: Brandy Harris, Reilly, McDevitt, 20 Henrich, on behalf of Firsthealth Care Products. 21 ANALISA DiFEO, Ph.D., 22 having first been duly sworn, was examined and testified 23 on her oath as follows: 24 MS. THOMPSON: Dr. DiFeo, I'm Margaret 25 Thompson, and I am representing the plaintiffs.	Page 7		<p>1 Q. And I want to say up front that I am impressed with your 2 work and your research, and I do not want to be 3 disrespectful in any way if I disagree with some of your 4 opinions, fair?</p> <p>5 A. Fair.</p> <p>6 Q. Okay. So there are a couple things that make it easier, 7 especially for our court reporter, Laura, and that's 8 where we'll try to do our best to talk slowly and 9 clearly. I have a tendency to talk a little fast, so 10 I'm going to try to slow down. And also, particularly 11 with Zoom, we need to give each other a little time 12 before we start back up. If there's a pause, just wait 13 maybe a little longer than we would be in person. Does 14 that make sense?</p> <p>15 A. Yes.</p> <p>16 Q. And if Ms. Sharko has an objection, give her time to 17 make that objection before you answer the question. But 18 in those instances, you'll still be able to answer the 19 question unless she instructs you not to for some 20 reason. Fair?</p> <p>21 A. Understood.</p> <p>22 Q. And if you do need to take a break at any time, just let 23 me know and we can do that. Otherwise, we'll try to 24 take a break every hour, hour and a half, fair?</p> <p>25 A. Okay. That sounds good.</p>

<p style="text-align: right;">Page 10</p> <p>1 Q. Okay. And if there's a question that you don't 2 understand -- and I have been known to ask bad 3 questions -- just let me know, and I'll try to rephrase 4 it so that it is understandable. There's nothing today 5 that is meant to be a trick or anything other than just 6 my trying to understand your opinions. Fair enough?</p> <p>7 A. Sounds good.</p> <p>8 MS. THOMPSON: Okay. So let's go ahead and --</p> <p>9 Laura, you have marked our first several 10 exhibits, correct?</p> <p>11 COURT REPORTER: Yes. Correct.</p> <p>12 MS. THOMPSON: I'm sorry, I don't mean to ask 13 a question with a correct at the end, but we have the 14 first several exhibits marked. Exhibit 1, Dr. DiFeo, is 15 your expert report.</p> <p>16 DEPOSITION EXHIBIT 1</p> <p>17 Expert Report of Dr. Analisa DiFeo</p> <p>18 WAS MARKED BY THE REPORTER</p> <p>19 FOR IDENTIFICATION</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. And how did you go about producing this report?</p> <p>22 A. So how I like -- how I typically do these type of -- 23 when I'm asked a question, scientific question, I like 24 to do a literature -- a very thorough literature review, 25 and I pull every -- I try to pull every article that</p>	<p style="text-align: right;">Page 12</p> <p>1 BY MS. THOMPSON:</p> <p>2 Q. Did you use a search engine?</p> <p>3 A. Yes. So typically -- in our field, there's something 4 called PubMed. That's one of the first search engines 5 we use, and that is primarily what I used.</p> <p>6 Q. And what search terms did you use?</p> <p>7 A. So I can't tell you every search term because I 8 search -- again, this is my field, so I do this 9 periodically. And I can't remember everything, but I 10 can tell you I use talc, talcum powder, ovarian cancer, 11 combination of those. And the other thing is, I get 12 weekly updates from NCBI and PubMed if any new papers 13 come out that include those keywords. So I don't have 14 to search it myself. I will get alerts if any papers 15 come out with those keywords in them.</p> <p>16 Q. And the citations in your report, can I assume that 17 those were the articles that you felt most relevant to 18 the information that you provided?</p> <p>19 A. Yes.</p> <p>20 MS. THOMPSON: Let's go ahead and mark your CV 21 as Exhibit 2 and have that in front of you.</p> <p>22 DEPOSITION EXHIBIT 2</p> <p>23 Curriculum Vitae of Dr. Analisa DiFeo</p> <p>24 WAS MARKED BY THE REPORTER</p> <p>25 FOR IDENTIFICATION</p>
<p style="text-align: right;">Page 11</p> <p>1 discusses the key topics. So, for instance, if, for 2 this case, or this review, I was looking at the role of 3 talc in ovarian cancer, and given that I have worked in 4 ovarian cancer for close to 20 years, I've already 5 essentially reviewed this type of work for the continuum 6 of my career, but I had not necessarily taken a deep 7 dive into talc. So I spent a lot of time pulling all 8 those papers.</p> <p>9 In addition to that, Susan and Eric also 10 provided papers that included research on talc, and I 11 just went about describing some of the studies. I also 12 gave a brief background on ovarian cancer and cancer in 13 general. And since my lab works on identifying factors 14 that are involved in the initiation, progression, and 15 the key factors that are responsible for diseases 16 recurrence, I also wanted to explicitly try to explain 17 how we go about identifying those factors in this report 18 in the most thorough way, but not --</p> <p>19 Q. And --</p> <p>20 A. Sorry.</p> <p>21 MS. SHARKO: No. Let Dr. DiFeo finish her 22 answer.</p> <p>23 MS. THOMPSON: No. You have the floor.</p> <p>24 THE WITNESS: In the most thorough way. So 25 that's how I did it.</p>	<p style="text-align: right;">Page 13</p> <p>1 BY MS. THOMPSON:</p> <p>2 Q. And, Dr. DiFeo, go ahead and just tell me a little bit 3 about your position and your research and your 4 laboratory. This is just an opportunity for you to tell 5 me about what you do.</p> <p>6 A. Sure. So I am -- I was just promoted to professor in 7 the department of pathology at the University of 8 Michigan.</p> <p>9 Q. Congratulations.</p> <p>10 A. Thank you. And I run the Michigan Ovarian Cancer 11 Consortium and Innovation Program, which is a statewide 12 consortium that focuses on ovarian cancer research. 13 Through this program, we, with a group of physicians, 14 scientists, bioinformaticians, pathologists, the 15 ultimate mission of my lab and this consortium is to 16 work with patients and patient advocates to discover the 17 key factors that are involved in ovarian cancer 18 progression, with the ultimate goal to uncover novel 19 biomarkers and drug targets to improve the survival of 20 women that are diagnosed with cancer. How we do this, 21 through the development of a tissue biobank that I have 22 started at every institution I've been at. So I trained 23 at Mount Sinai Hospital, that's where got my Ph.D. Then 24 I was in Cleveland at Case Western Reserve University. 25 And now I've been at University of Michigan for five</p>

<p style="text-align: right;">Page 14</p> <p>1 years. And at all three institutions, I was the 2 director of the tissue biobank in gyn pathology. And 3 through all of those programs, I was able to obtain 4 tissue samples from patients. So the research we do in 5 our lab is patient driven. Every question we ask and 6 every experiment we do is based on what we see from the 7 patient samples.</p> <p>8 So it's -- as we know, cancer is a genetic 9 disease, so we utilize those patient samples to uncover 10 what genetic alterations are driving these tumors. And 11 with that information, we try to uncover what biomarkers 12 we can use for prognosis or drug discovery.</p> <p>13 Q. Would you agree that your laboratory is primarily 14 devoted to targeting therapeutics for women who already 15 have ovarian cancer?</p> <p>16 A. No.</p> <p>17 Q. Are you involved at all with the early detection of 18 ovarian cancer?</p> <p>19 A. Yes.</p> <p>20 Q. So in women who do not have ovarian cancer yet, you're 21 looking at ways to diagnose it earlier?</p> <p>22 A. Oh, yes. So, for instance, we just got -- I just got an 23 R01 with Geeta Mehta to actually assess whether 24 fallopian tube cells shed from the fallopian tube due to 25 shear stress. And, actually, you can see that in my CV,</p>	<p style="text-align: right;">Page 16</p> <p>1 Research Alliance, and Eli Lilly Research Award is the 2 R21 and R01 funding through NCI.</p> <p>3 Do you receive any Johnson & Johnson funding 4 in your laboratory?</p> <p>5 A. No.</p> <p>6 Q. Does University of Michigan, to your knowledge, receive 7 research funding from Johnson & Johnson?</p> <p>8 A. Oh, I don't know that. It's a huge university. I 9 wouldn't know. I don't know.</p> <p>10 Q. Okay. It wouldn't surprise you if it did, would it?</p> <p>11 A. I honestly do not know. I have no clue.</p> <p>12 Q. Okay. Let's go ahead and mark as Exhibit 3 the 13 materials reviewed and considered.</p> <p>14 DEPOSITION EXHIBIT 3</p> <p>15 Materials Reviewed and Considered</p> <p>16 WAS MARKED BY THE REPORTER</p> <p>17 FOR IDENTIFICATION</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. And this is a list of references that are not actually 20 cited in your report, but that you, obviously, 21 considered in writing your report, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Did you create this list or someone else?</p> <p>24 A. This list, I think, was created by Eric.</p> <p>25 Q. Okay. And you're referring to Mr. Friedman, who's one</p>
<p style="text-align: right;">Page 15</p> <p>1 it's the most recent R01 from the NIH. 2 In addition to that, we just published a 3 Nature communications paper looking at the 4 transformative ability of this microRNA 181 in the 5 fallopian tube. 6 In addition to that, you'll see that I just 7 served as a reviewer at the NIH to review grants for a 8 consortium that's looking to collect early-stage 9 precursor lesions of the fallopian tube. And in order 10 to be a reviewer on those NIH review committees, you 11 have to be an expert in the field. So these are now NIH 12 employees that have decided that I am an expert in that 13 field and, therefore, they asked me to be on that review 14 committee. So I think, given that, I'm not the one who 15 thinks, obviously, they decided that I'm an expert and 16 asked me to be a reviewer on that committee. 17 Q. And what is that consortium? 18 A. It's H10. You can -- it's in my CV. 19 Q. Okay. On page 3 of your report, you talk about the 20 funding of your laboratory. 21 A. Yes. Okay. 22 Q. And you list the Department of Defense, several -- are 23 you there? Sorry. I didn't want to rush you. 24 A. Of course, yes. 25 Q. So Mary Kay Foundation awards the Ovarian Cancer</p>	<p style="text-align: right;">Page 17</p> <p>1 of the attorneys? 2 A. (Shaking head affirmatively.) 3 Q. Who first contacted you about the possibility of serving 4 as an expert witness in this case? 5 A. Susan. 6 Q. And when was that? 7 A. Oh, I don't remember the exact date. I believe it was 8 in 2022, or -- what are we in, '24? Yeah, 2022. 9 Because -- yeah. But -- 10 Q. Okay. 11 A. -- then we were not in contact for a while, that's why I 12 don't recall exactly. Because I know we weren't in 13 contact for a year. There was a break for a while, so 14 that's why I don't remember exactly. 15 Q. Okay. And if I interrupt like that, it was just 16 thinking you were finished, but always want you to be 17 able to complete your answer. 18 And we're going to look at invoices in a 19 little while that may help with the answer to that 20 question. 21 But I noticed on the Materials Reviewed and 22 Considered list you state that it's medical, scientific 23 and regulatory references and literature? 24 You are not a medical doctor, correct? 25 A. No, I'm not.</p>

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<p>1 Q. Are you intending to give medical opinions in this case?</p> <p>2 MS. SHARKO: Object to the form.</p> <p>3 You can answer.</p> <p>4 THE WITNESS: I can?</p> <p>5 MS. SHARKO: Yes.</p> <p>6 THE WITNESS: Oh, okay. Sorry, I didn't know</p> <p>7 what that meant. Sorry.</p> <p>8 MS. SHARKO: Yeah.</p> <p>9 THE WITNESS: In my medical opinion -- so I</p> <p>10 don't -- maybe I don't quite understand the question.</p> <p>11 Am I giving my medical opinion. So I don't -- I don't</p> <p>12 see patients, however, in the clinic. I do see patients</p> <p>13 quite often, given my role in terms of being --</p> <p>14 interacting with patients and patient advocates and the</p> <p>15 research I do and the laboratories I do. So I'm on the</p> <p>16 board of the Michigan Ovarian Cancer Alliance and being</p> <p>17 part of MOSAIC, which I mentioned is that statewide</p> <p>18 consortium. And given that I am very passionate about</p> <p>19 ovarian cancer research and building the awareness</p> <p>20 around ovarian cancer, I do interact with patients. And</p> <p>21 I think it is essential that patients know the</p> <p>22 information, know the risk factors, know the research</p> <p>23 that's being done and therapies that are available to</p> <p>24 them.</p> <p>25 BY MS. THOMPSON:</p>	<p>1 Q. Let's say case-specific opinions, will you be providing</p> <p>2 any case-specific opinions on those six plaintiffs?</p> <p>3 A. No. So I guess you asked, there were two questions.</p> <p>4 You asked if I reviewed the genetic reports. I did</p> <p>5 review the genetic reports and, unfortunately, after the</p> <p>6 review -- so my Ph.D. was in cancer genetics at Mount</p> <p>7 Sinai, I got -- I was in the department of genetics. So</p> <p>8 I was very curious and interested to see the genetic</p> <p>9 reports. As we know, cancer's a genetic disease and</p> <p>10 it's important to understand that. And there were some</p> <p>11 interesting findings there, however, it was</p> <p>12 disappointing because what I noticed from many of those</p> <p>13 reports and why I did not include it in the final report</p> <p>14 was that many of the patients lacked the</p> <p>15 state-of-the-art genetic testing that's commonly used.</p> <p>16 So I could not come up with a conclusive opinion without</p> <p>17 the sufficient data. So that's why I did not include</p> <p>18 it.</p> <p>19 Q. So at least at this point in time, are all the opinions</p> <p>20 that you plan to offer at trial contained in your actual</p> <p>21 report?</p> <p>22 A. So I don't know -- I mean, again, my -- if asked my</p> <p>23 opinion on whether talc causes ovarian cancer, it's</p> <p>24 clearly stated in the report, it does not change. The</p> <p>25 data presented to me clearly states or shows that talc</p>
Page 19	Page 21
<p>1 Q. Do you examine women with ovarian cancer?</p> <p>2 A. I do not examine them.</p> <p>3 Q. Do you diagnose women with ovarian cancer?</p> <p>4 A. I do not diagnose.</p> <p>5 Q. Do you prescribe treatment for women with ovarian</p> <p>6 cancer?</p> <p>7 A. No.</p> <p>8 Q. Do you intend to give regulatory opinions in this case?</p> <p>9 A. No. I was asked a very specific question, my opinion on</p> <p>10 the role of talc in driving ovarian cancer</p> <p>11 transformation, and I clearly stated that it does not.</p> <p>12 Q. And do you have any expertise in regulatory matters?</p> <p>13 A. I think I've answered I don't have -- regulatory issues</p> <p>14 are not in my area of expertise.</p> <p>15 Q. And so your -- I noticed on your -- on the materials</p> <p>16 considered that you did look at the medical records of</p> <p>17 the six trial plaintiffs in this case. Am I right?</p> <p>18 A. That's correct.</p> <p>19 Q. Will you be giving any opinions regarding those</p> <p>20 patients?</p> <p>21 MS. SHARKO: You mean -- object to the form of</p> <p>22 the question. I assume you mean case-specific opinions,</p> <p>23 Margaret?</p> <p>24 MS. THOMPSON: Yeah.</p> <p>25 BY MS. THOMPSON:</p>	<p>1 is not involved or initiates ovarian cancer.</p> <p>2 Q. Fair enough. And, of course, if I ask you a question</p> <p>3 today and you provide an answer, that certainly would be</p> <p>4 included in what you would testify to at trial,</p> <p>5 understood?</p> <p>6 A. If I was asked at trial, yes.</p> <p>7 Q. And your Ph.D. is in what field?</p> <p>8 A. So Mount Sinai is a hospital, and you get your Ph.D.</p> <p>9 from NYU, actually, which is the university it's</p> <p>10 affiliated with. So the Ph.D. is in -- it was a</p> <p>11 combination of cancer genetics, cancer biology. And as</p> <p>12 a Ph.D. -- your Ph.D. is really based on your thesis</p> <p>13 project. So my thesis was the role of KLF6 in ovarian</p> <p>14 cancer pathogenesis.</p> <p>15 Q. And that was in the genetics department?</p> <p>16 A. Yeah, the department of genetics at Mount Sinai.</p> <p>17 Q. Okay. So I have that right.</p> <p>18 Would you consider yourself -- this is related</p> <p>19 a little bit to a question previously, but I think it's</p> <p>20 a little different -- would you consider yourself a</p> <p>21 researcher rather than a clinician in regards to ovarian</p> <p>22 cancer?</p> <p>23 A. So what I consider myself is a translational researcher.</p> <p>24 Q. Okay.</p> <p>25 A. So if you were -- many times, actually, people confuse</p>

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<p>1 me as being an MD, given that my research is patient 2 driven. I collaborate intimately with the physicians 3 that oversee patient care. My lab is the bridge between 4 the hospital and the lab, and we collect patient samples 5 daily and all of the experiments that are done are on 6 patient samples. Therefore, we define that as 7 translational research, so -- researcher is a very vague 8 term; so therefore, we do translational research. I 9 just wanted to clarify that.</p> <p>10 Q. And thank you. That's a good explanation. 11 And so you would consider yourself a 12 translational researcher, but not a clinician, right?</p> <p>13 A. Not a clinician, yeah, I do not have an MD. But --</p> <p>14 Q. When you were first contacted by Ms. Sharko in 2022 or 15 approximately, did you already have an opinion as to 16 whether talc could cause ovarian cancer?</p> <p>17 A. Yes.</p> <p>18 Q. And what was that opinion?</p> <p>19 A. Exactly what I wrote in the report, that it does not.</p> <p>20 Q. And can we agree that if one or the other of us says 21 talc we're talking about talcum powder products?</p> <p>22 A. Yes.</p> <p>23 Q. And when we say ovarian cancer, can we agree that we're 24 talking about epithelial ovarian cancer, unless 25 specified otherwise?</p>	<p>Page 22</p> <p>1 BY MS. THOMPSON: 2 Q. Yeah, just so we're clear, Dr. DiFeo, what are the 3 subtypes of epithelial ovarian cancer, so we can include 4 those in the discussion?</p> <p>5 A. Yeah. So I stated them in the report, right, so 6 endometrial -- endometrioid, serous, mucinous, clear 7 cell. And I think that's -- did I say them all? Hold 8 on. I have to remember now.</p> <p>9 Yeah, serous, endometrioid, mucinous, clear 10 cell, yeah. Oh, and -- so you also want to include 11 low-grade serous; and, actually, borderline as well, you 12 also want to include borderline.</p> <p>13 Q. Okay. That gives us a general list to work with. And 14 if we are talking about a specific cell type, we'll 15 specify which one that is. Fair enough?</p> <p>16 A. Yeah. And I think that's very -- I'm happy you brought 17 that up because I think it's very important to specify, 18 given the various risk factors and the origin of where 19 they derive from.</p> <p>20 Q. Do you agree that much of the literature does not 21 distinguish between the various subtypes, agreed?</p> <p>22 A. No, I don't necessarily agree with that. If you're 23 reading the right literature, it does. Because 24 nowadays, we know enough about it, and scientists like 25 myself and my peers have really tried to make an effort</p>
<p>Page 23</p> <p>1 A. Well, you know, as you know, there's epithelial ovarian 2 cancer, but there's also other types of ovarian cancer. 3 So you want to just discuss epithelial ovarian cancer, 4 is what you're saying?</p> <p>5 Q. Well, if we just say ovarian cancer, if we're talking 6 about a subtype we'll specify the subtype, is that fair?</p> <p>7 A. Sure.</p> <p>8 Q. We're not talking about germ cell --</p> <p>9 A. Okay. Yeah.</p> <p>10 Q. -- germ cell or any other type of ovarian cancer.</p> <p>11 A. Okay.</p> <p>12 Q. Okay. That will probably make it a little easier.</p> <p>13 A. I agree. Yes.</p> <p>14 Q. Okay. Let's go to what we have not marked. Exhibit 4 15 is the Notice of Deposition.</p> <p>16 MS. SHARKO: So Margaret, I will just object 17 belated. I'm a little concerned by your suggestion, 18 Dr. Thompson, that any testimony here today does not 19 relate to clear cell cancer or does not relate to --</p> <p>20 THE WITNESS: I think she said germ cell.</p> <p>21 MS. SHARKO: Did you say germ cell?</p> <p>22 MS. THOMPSON: I said germ cell.</p> <p>23 MS. SHARKO: Oh, okay. Sorry. I thought you 24 said clear cell.</p> <p>25 MS. THOMPSON: And --</p>	<p>Page 25</p> <p>1 to distinguish it, and we're hoping to change that 2 because that's the issue of why the mortality is so low. 3 Because it hasn't been distinguished enough and why 4 we're trying to build awareness around ovarian cancer.</p> <p>5 Q. Okay. Fair enough.</p> <p>6 And when we look at individual articles, we 7 can determine whether they're speaking to a certain 8 subtype or most subtypes or comparing the subtypes, 9 fair?</p> <p>10 A. Yes. And that's why it's critical to have the right 11 reviewers review papers and go to the correct journals, 12 because we need to be very specific in our words and our 13 details on the types of cancers.</p> <p>14 Q. And --</p> <p>15 MS. SHARKO: Wait. Were you finished?</p> <p>16 THE WITNESS: Yes.</p> <p>17 MS. THOMPSON: Agreed.</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. We agree that most of the epidemiological literature 20 regarding the relationship of talcum powder to ovarian 21 cancer does not distinguish between the various 22 subtypes. Not all, but most if not.</p> <p>23 A. To be -- I'm a cancer biologist, I'm not an 24 epidemiologist. I have not focused all of my efforts in 25 reading every single one of the epidemiological studies</p>

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<p style="text-align: right;">Page 26</p> <p>1 in full detail, so I don't -- I can't answer that 2 question with the fullest confidence to say that they 3 haven't looked at -- or done a deep dive at 4 distinguishing all the subtypes.</p> <p>5 Q. Okay. And I did notice that you did not include any of 6 the epidemiology literature in your report except for 7 the recent O'Brien study, is that right?</p> <p>8 A. Yeah. As I mentioned, I focus on the mechanisms, the 9 biology, the functional impact of associations that are 10 made, given that that's my expertise. I collaborate 11 with epidemiologists, who then come to me and ask me to 12 validate their findings. However, that's not my area of 13 expertise, so I did not include that in my report.</p> <p>14 There's other experts that I believe could do a much 15 better job in explaining the studies that have been 16 published.</p> <p>17 Q. And you must have read my mind because that was my next 18 question, is, was the reason that you did not include 19 any epidemiology studies in your report is because 20 that's not your area of expertise, is that fair?</p> <p>21 A. That's correct, yes. I like to collaborate with people, 22 and if I know that they're experts at it, I'd rather 23 them give their opinion in that area.</p> <p>24 Q. Sure. Let's -- Exhibit 4 has already been marked as the 25 Notice of Deposition.</p>	<p style="text-align: right;">Page 28</p> <p>1 I've never been deposed before, so I didn't -- I don't 2 know the process, so a lot of the conversation was --</p> <p>3 MS. SHARKO: Well, wait. What was discussed 4 is privileged.</p> <p>5 THE WITNESS: Oh, yeah, sorry.</p> <p>6 MS. SHARKO: So you can't talk about what was 7 discussed.</p> <p>8 THE WITNESS: Okay. Sorry. What was the 9 question? Sorry. So yeah, we just met --</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. So when did the meeting take place, who did you meet 12 with and how long did each meeting last? Let's be more 13 specific, that might make it easier.</p> <p>14 A. So the meetings were with Susan and Eric, and they were 15 over Zoom and they were typically an hour, sometimes an 16 hour and a half, two hours long.</p> <p>17 Q. And the --</p> <p>18 MS. THOMPSON: Let's go ahead and put the 19 invoices in front of you because that's a good segue 20 into those. And they're marked as Exhibit 5.</p> <p>21 DEPOSITION EXHIBIT 5</p> <p>22 Invoices for Consulting Services</p> <p>23 WAS MARKED BY THE REPORTER</p> <p>24 FOR IDENTIFICATION</p> <p>25 BY MS. THOMPSON:</p>
<p style="text-align: right;">Page 27</p> <p>1 DEPOSITION EXHIBIT 4</p> <p>2 Notice of Deposition</p> <p>3 WAS MARKED BY THE REPORTER</p> <p>4 FOR IDENTIFICATION</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. Have you seen this document?</p> <p>7 A. Yes.</p> <p>8 Q. Did you meet with Ms. Sharko and Mr. Friedman prior to 9 this deposition?</p> <p>10 A. Yes.</p> <p>11 Q. And when were the -- tell me about those meetings. When 12 did they take place, how long did they last, who did you 13 meet with? Those kinds of details.</p> <p>14 MS. SHARKO: Well, I'm going to --</p> <p>15 MS. THOMPSON: But don't tell me what was 16 discussed.</p> <p>17 MS. SHARKO: Okay. So what was discussed at 18 the meetings is privileged.</p> <p>19 THE WITNESS: Oh, okay.</p> <p>20 MS. SHARKO: You can tell her when, where the 21 meetings were.</p> <p>22 THE WITNESS: Oh. So when -- I mean, I don't 23 remember the exact dates. It was various times over the 24 last month or two months. It was over Zoom. And we -- 25 you know, as you mentioned I think in the beginning,</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Do you have those in front of you?</p> <p>2 A. Yes.</p> <p>3 Q. Dr. DiFeo?</p> <p>4 A. Yes, I do.</p> <p>5 Q. With those in front of you, I'm going to go back to the 6 Notice of Deposition that hopefully is in front of you 7 as well.</p> <p>8 A. Yes.</p> <p>9 Q. And you said you have seen that. Did you bring any 10 materials with you today?</p> <p>11 A. No.</p> <p>12 MS. THOMPSON: And, Susan, I know you've filed 13 objections and we are aware of those.</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. Looking at your invoices, Dr. DiFeo, it looks like the 16 first invoice is -- takes place from September of 2021 17 to February 2022. And would that refresh your memory 18 perhaps on when you first started working on this 19 litigation?</p> <p>20 A. Yes. Sorry, I said '22. It was 2021.</p> <p>21 MS. SHARKO: Object to the form of the 22 question. It says August there.</p> <p>23 MS. THOMPSON: Yeah. August 2021?</p> <p>24 MS. SHARKO: Yes.</p> <p>25 MS. THOMPSON: Did I say something else?</p>

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1 MS. SHARKO: You said September. 2 MS. THOMPSON: Oh. I'm sorry. 3 MS. SHARKO: That's okay. We got it. 4 MS. THOMPSON: Yeah. 5 BY MS. THOMPSON: 6 Q. So that would suggest that you started working on the 7 litigation August of 2021? 8 A. Yeah. 9 Q. And the invoices go through, I think, May of this year. 10 Let me check the date. No, March 28th, '24. Do you 11 agree? 12 A. March, yep. 13 MS. SHARKO: Look at the -- 14 THE WITNESS: Oh, there's one behind there. 15 No, there's another one. 16 BY MS. THOMPSON: 17 Q. Is there another one that we don't have? 18 MS. SHARKO: There's -- we sent you one after 19 the -- we sent you one in the last day or two that came 20 from Mr. Friedman, I think. 21 MS. THOMPSON: Okay. I may not have that one. 22 Do you have that with you, Dr. DiFeo? 23 THE WITNESS: I have that with -- sorry, can 24 you repeat the question? 25 BY MS. THOMPSON:	1 MS. SHARKO: You have to answer yes or no. 2 THE WITNESS: Yes. I did. 3 MS. SHARKO: Okay. I thought you were saying 4 yeah. 5 THE WITNESS: Oh, I said yes. 6 MS. SHARKO: Okay. Good. 7 THE WITNESS: Yes. 8 MS. THOMPSON: And I know this is your first 9 time testifying, and so we'll give a little leeway, you 10 know, if you do have questions about the process, as 11 well as answers. You can't ask Ms. Sharko about your 12 answers to specific questions, but I'm fine allowing you 13 to clarify a procedural question, fair? 14 THE WITNESS: So I didn't have a question. I 15 said yes. 16 MS. THOMPSON: No, I'm just -- 17 MS. O'DELL: Excuse me. I can't hear very 18 well. Is there any way that the phone could be moved 19 closer to Dr. DiFeo? 20 MS. SHARKO: Yes. We'll do that. 21 And I'm sorry, it sounded to me like Dr. DiFeo 22 was saying yeah, and so I just wanted to make sure the 23 record was clear and I told her you have to answer yes 24 or no, you can't say yeah. That was what the last three 25 seconds were.
1 Q. Do you have a more recent invoice with you today after 2 March 28th, 2024? 3 MS. SHARKO: Margaret, it's part of the 4 deposition exhibits. 5 THE WITNESS: You just gave it to me. 6 MS. SHARKO: You have it there. 7 MS. THOMPSON: Okay. I just didn't get it 8 into my set of documents. 9 BY MS. THOMPSON: 10 Q. So let's go through the ones I have, and then I may ask 11 you questions about the most recent one, if you have it 12 with you. 13 So the amount through February of 2022 would 14 total \$77,000, is that correct? Or any reason to 15 disagree with that? 16 A. I don't know. I didn't calculate it all. I don't know 17 exactly how much it was. I didn't calculate the total 18 amount. 19 Q. And you're charging \$750 an hour, is that correct? 20 A. That's correct. 21 Q. And that includes any work that you do, whether it be 22 review of literature or deposition or trial testimony? 23 A. Yes. 24 Q. The rate is the same? 25 A. Yes.	1 MS. THOMPSON: Yeah. And I just said yeah as 2 well, to make an example, and that was good, but I -- so 3 it was suited for me as well. 4 THE WITNESS: Can you hear me better now? I 5 don't know who mentioned that, but can you hear me 6 better? 7 MS. O'DELL: Yes. Thank you very much. 8 BY MS. THOMPSON: 9 Q. It appears that the work done in this first phase was 10 primarily reviewing records and writing a report, your 11 report, is that a fair understanding? 12 A. That is correct. 13 Q. And you continued to do work October 21st to 14 February 22nd, and that time frame would have been after 15 the -- J&J's first bankruptcy was initiated. Were you 16 aware of that? 17 A. I did not follow a lot of the J&J loss, bankruptcy. I 18 was focused on writing the report. And I was given 19 deadlines of when, like, in my mind, pretty much, of 20 when the report was due and when I wanted to have it 21 done. I wasn't sure about what was going on on the J&J 22 side or the legal side. So I don't -- I can't answer 23 anything about the bankruptcy issues or legal 24 implications. I don't know any of that. 25 Q. That's fair. It looks like you resumed work again in

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<p style="text-align: right;">Page 34</p> <p>1 December of '23, and this looked like it was more in the 2 arena of reviewing expert reports, updating your report, 3 and reviewing the plaintiffs' medical records. Is that 4 fair?</p> <p>5 A. That started at -- it was in October of '23. Is that 6 the one you're referring to? And November of '23?</p> <p>7 Q. Yes.</p> <p>8 A. It was an invoice -- December -- December 23rd invoice, 8 9 but the review of the literature, again, was in October 10 into November of '23, yeah.</p> <p>11 Q. And on that -- looking at, Dr. DiFeo, on the invoice of 12 March 2024, one of the entries is review of the, I think 13 that's Mandarino and the asbestos paper. Had you read 14 the Mandarino in any paper prior to that date?</p> <p>15 A. Are you -- oh, this, the January 23rd, '24?</p> <p>16 Q. No. The March 19th, 2024.</p> <p>17 A. Oh, that invoice. Okay. Yeah. Yeah, the date 18 associated with it is January -- I had --</p> <p>19 Q. I'm sorry, the date associated -- sorry. The date 20 associated with the review of the Mandarino and Emi 21 papers was January 23rd, 2024. Had you reviewed those 22 papers previous to that?</p> <p>23 A. I had not.</p> <p>24 Q. And it says and asbestos paper. Do you know what the 25 asbestos paper was?</p>	<p style="text-align: right;">Page 36</p> <p>1 asbestos as a risk factor or a cause of ovarian cancer 2 are irrelevant?</p> <p>3 A. So, again, I think asbestos is not something I explored 4 thoroughly, so I don't want to really give a -- I don't 5 feel comfortable giving an in-depth opinion. However, 6 my opinion is this: If there is any suggestion that 7 asbestos is in talcum powder or talc, I do not think it 8 plays a role in ovarian cancer pathogenesis, because 9 from the data that I reviewed and the research that's 10 been published, if asbestos did play a role, it would be 11 present in the talc that was tested. And from all of 12 those studies, talc did not show to play a role or have 13 an effect in the transformation of ovarian cancer cells.</p> <p>14 Q. Okay. I want to try to break that down a little bit and 15 then we'll get back to the invoices. But while we're on 16 that, so am I correct that you did not do any 17 comprehensive review of the relationship between 18 asbestos and ovarian cancer?</p> <p>19 A. I did not -- I did not look at the role of asbestos on 20 ovarian cancer, no.</p> <p>21 Q. And did you do any research as to the mechanism by which 22 asbestos could cause ovarian cancer?</p> <p>23 MS. SHARKO: Object to the form of the 24 question.</p> <p>25 You can answer.</p>
<p style="text-align: right;">Page 35</p> <p>1 A. I didn't -- I don't. And as you can see there, I did a 2 lot during that time, and I think I -- so I wanted to 3 update my previous review from year prior, and the 4 reason I read the Mandarino and Emi paper is because it 5 was a new paper that popped up on talc and ovarian 6 cancer, and I -- there was some, I think, talk about 7 potentially asbestos being associated with talc, so I 8 kind of perused some of the asbestos paper, then I 9 realized it really wasn't relevant to the question I had 10 at hand, so I didn't pursue that any further. And as 11 you can see, I didn't include that in my report because 12 it was not relevant to the question. So I don't recall 13 what paper it was, because I didn't think -- it was not 14 relevant. And it didn't alter my opinion, given that 15 the question was whether talc played a role in ovarian 16 cancer, and the papers I was reading, such as the 17 Mandarino and Emi, were really the only ones that tried 18 to assess that, in a somewhat indirect way. But I 19 thought that that was important to include because they 20 did attempt to determine the role of talc in ovarian 21 cancer.</p> <p>22 Q. And we'll get into the specific literature a little bit 23 later, so you'll have an opportunity to give opinions on 24 individual papers.</p> <p>25 Is it your view that any papers relating to</p>	<p style="text-align: right;">Page 37</p> <p>1 THE WITNESS: Answer? 2 From my 20 years of ovarian cancer research, I 3 have not -- and again, I have pretty much looked at 4 many, many, many papers looking at the mechanisms that 5 drive ovarian cancer transformation. I do not recall 6 any paper that has shown that asbestos plays a role in 7 the transformation of ovarian cancer. So though I may 8 not have looked at it for this --</p> <p>9 Q. And --</p> <p>10 A. I'm sorry.</p> <p>11 MS. SHARKO: No. Keep going. Finish your 12 answer.</p> <p>13 THE WITNESS: I may not have looked at it for 14 this report, but I know in terms of the mechanistic role 15 of asbestos and ovarian cancer, there's no evidence of 16 that.</p> <p>17 MS. THOMPSON: And any time it appears that 18 I'm interrupting you, you have the floor, so I'll back 19 off. Okay. It was accidental.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. In your view, in transformation, in your words, a 22 requirement for an agent or condition to contribute or 23 cause ovarian cancer?</p> <p>24 A. Yes. To cause any cancer.</p> <p>25 Q. Okay. I apologize for skipping around a little bit</p>

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<p style="text-align: right;">Page 38</p> <p>1 here. Let's go back to the invoices because I think we 2 had -- the last one I have is dated May 27th, '24, at 3 least the last one I have with me today. And the total 4 of the invoices up to May 27th, 2024, would be \$128,000 5 and -- \$128,050. Do you have any reason to dispute 6 that?</p> <p>7 A. Again, I have not calculated, I don't know off the top 8 of my head, so I can't speak to how much the total was, 9 the sum.</p> <p>10 Q. Is that work all for the MDO? Do you understand what 11 the MDO is?</p> <p>12 A. I don't know what that acronym stands for.</p> <p>13 Q. Multi-district litigation.</p> <p>14 MS. SHARKO: Dr. DiFeo has been identified as 15 an expert in Carl, Bolderama, and the MDO cases, if that 16 helps you.</p> <p>17 MS. THOMPSON: Okay.</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. So those invoices would include the work on the Carl, 20 Bolderama, and the Multidistrict litigation, is that 21 right?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Have you ever been disclosed in any other cases? 24 And this is only -- these would only be cases that 25 you've actually been disclosed?</p>	<p style="text-align: right;">Page 40</p> <p>1 projects I have in the lab, it would be hard for me to 2 distinguish the hours that I'm devoting to this or the 3 grants that I'm writing or the papers that I'm putting 4 together, so I'm sorry, I can't distinguish that, that's 5 why -- it's hard.</p> <p>6 Q. Understood. And I think that 24/7 thinking about 7 ovarian cancer would apply to many of us in this room. 8 Can you just tell me the date of the invoice 9 that you have with you that I don't have and the total?</p> <p>10 A. I think you mentioned it actually. It's May 27th, 2024. 11 Is that -- I thought that was a date you just said.</p> <p>12 Q. Is that the most recent one?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Then we do have everything. Have you submitted 15 an invoice since that time?</p> <p>16 A. No.</p> <p>17 Q. Okay. Let's get into your report in a little bit more 18 detail, Dr. DiFeo. And if we could turn in your report 19 to page 6. And I want to just go over some of the -- 20 the scope of your report and the summary of your 21 opinions are contained on that page, correct?</p> <p>22 A. Yes.</p> <p>23 Q. The first sentence under Scope of Report, This report 24 reflects my analysis and opinions based on my education, 25 training, and expertise as a cancer biologist, and a</p>
<p style="text-align: right;">Page 39</p> <p>1 A. I don't -- I believe not, no.</p> <p>2 Q. And Ms. Sharko can help with you that answer if there's 3 a question.</p> <p>4 A. (No response.)</p> <p>5 Q. Did you answer? I'm not sure.</p> <p>6 A. No. I think she helped answer.</p> <p>7 Q. Okay.</p> <p>8 A. She explained to it me.</p> <p>9 MS. SHARKO: No, Dr. DiFeo has not been 10 disclosed in any other cases at this time.</p> <p>11 BY MS. THOMPSON:</p> <p>12 Q. The most recent invoice I apparently don't have, 13 approximately, how many hours have you spent on this 14 case between May 27th and today?</p> <p>15 A. Oh, I don't know. I don't -- I haven't checked. I 16 haven't looked back at -- I'm sorry, I don't know off 17 the top of my head. I -- research and science are on my 18 mind 24 hours a day. This is my profession. I'm 19 thinking about ovarian cancer 24 hours a day pretty 20 much. So it would be hard for me to distinguish the 21 two. So to think about how many hours I'm thinking 22 about this or my research -- I work on fallopian tube 23 transformation in my lab, so we have fallopian tube 24 cells growing in the incubators in my lab, so to think 25 whether it's about for this case or the ten research</p>	<p style="text-align: right;">Page 41</p> <p>1 thorough review of the relevant literature on the issue 2 of whether cosmetic talc causes or contributes to 3 ovarian cancer.</p> <p>4 By cancer biologist, is that an equivalent 5 term to the translational research that you described 6 earlier?</p> <p>7 A. Yes.</p> <p>8 Q. And it's your opinion -- let's go down to the actual 9 Summary of Opinions. And your opinion, stated in 10 Summary of Opinions, is based on my education and 11 experience, I conclude that cosmetic talc, regardless of 12 the exact constituents or alleged contaminants, does not 13 cause or contribute to the development of ovarian 14 cancer.</p> <p>15 Is that the essence of your opinions in this 16 case?</p> <p>17 A. Yes.</p> <p>18 Q. And is it your understanding that talcum powder is a 19 cosmetic?</p> <p>20 A. So talc is a finely-ground mineral, and for purposes of 21 this report I focused on cosmetic talc. A lot of the 22 studies, several of the studies that I analyzed utilized 23 cosmetic talc and the role of cosmetic talc in 24 transformation. But, however, as you just read, some of 25 them also use purified talc, and that's why I stated,</p>

<p style="text-align: right;">Page 42</p> <p>1 regardless of the exact constituents and alleged 2 contaminants, I want to specify in various forms of it, 3 I did not see evidence that talc, in its various forms, 4 contributed to ovarian cancer pathogenesis or 5 development.</p> <p>6 Q. And that was an instance where I think where I didn't 7 ask a very clear question, so I want to ask that again. 8 Specifically referring to Johnson's Baby Powder, and 9 Shower to Shower. Is it your understanding that those 10 were the two talcum powder products manufactured and 11 sold by Johnson & Johnson?</p> <p>12 A. Is that my -- yes.</p> <p>13 MS. SHARKO: Object to the form of the 14 question, sold by Johnson & Johnson.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Sorry. Manufactured by -- let's leave it at 17 manufactured by Johnson & Johnson?</p> <p>18 MS. SHARKO: Same objection.</p> <p>19 THE WITNESS: Can you repeat the question?</p> <p>20 Sorry.</p> <p>21 MS. THOMPSON: Yeah. I'm going to try and 22 repeat it without an objection.</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Is it your understanding that the Johnson & Johnson 25 talcum powder product at issue in this case are</p>	<p style="text-align: right;">Page 44</p> <p>1 is to determine whether something -- and in this case 2 was talc in all of the forms that were tested in all the 3 literature I read -- played a role in causing ovarian 4 cancer. Therefore --</p> <p>5 Q. Do you agree with me --</p> <p>6 A. Sorry, I'm not done. Therefore, regardless of what was 7 in the products, which I cannot speak to, what I saw was 8 that it did not play a role in driving ovarian cancer 9 pathogenesis or development.</p> <p>10 Q. And you did, however, review virtually all of the expert 11 reports for the plaintiffs, is that right?</p> <p>12 A. No. No, I did not. I was given them, but I didn't -- 13 it was impossible to review everything. I perused 14 various things. I really focused on the data, the 15 research, given that I think it's important to analyze 16 everything in as much depth as you can and look at the 17 preliminary data. Science, research, is about data. 18 And as I tell my trainees, the data is what speaks to 19 you and you have to base it on rigorous reproducible 20 data.</p> <p>21 Q. Do you know what the constituents of Johnson's Baby 22 Powder and Shower to Shower are?</p> <p>23 A. I think I answered that question. I told you, to me, it 24 wasn't about the constituents, it was about looking at 25 all the articles that utilize various forms of talc with</p>
<p style="text-align: right;">Page 43</p> <p>1 Johnson's Baby Powder and Shower to Shower?</p> <p>2 A. I don't know -- I believe so.</p> <p>3 Q. And are those two products considered cosmetic products?</p> <p>4 A. So, you know, I'm not in manufacturing, I don't -- I've 5 never worked for large companies like J&J, so the term 6 cosmetic, again, I'm very specific on detail, it's 7 something maybe you could purchase over the counter. I 8 would assume those were cosmetic products. But again, 9 not my area of expertise.</p> <p>10 Q. Okay. And Dr. DiFeo, you know, I don't know or it's not 11 my area of expertise is always an acceptable answer, so 12 don't hesitate to give that answer if it's the right 13 one.</p> <p>14 Can I also assume that you, from a regulatory 15 standpoint, you don't know what would qualify or 16 constitute a cosmetic product?</p> <p>17 A. I don't work for regulatory agency, so I don't define 18 what would be a cosmetic product, that is correct.</p> <p>19 Q. Okay. And when you refer, in the primary opinions in 20 this case, what are those exact constituents or alleged 21 contaminants that have been addressed in this 22 litigation?</p> <p>23 A. I'm not -- I'm not going to go into specifics. I'm an 24 ovarian cancer translational researcher, as I mentioned. 25 And the goal of my career and the goal that I have here</p>	<p style="text-align: right;">Page 45</p> <p>1 whatever constituents were in the talc and assessing 2 whether talc in all of its forms and the constituents 3 that were in it played a role in ovarian cancer. And 4 what I found was, there was no evidence in all of the 5 literature I read that it had a mechanistic impact or 6 functional impact on the transformation or pathogenesis 7 of ovarian cancer.</p> <p>8 Q. And I'll object to that answer as non-responsive.</p> <p>9 MS. THOMPSON: When I do that, Laura, it just 10 means that I'm not sure you actually answered the 11 question that I asked.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. And the question was, do you know the constituents of 14 Johnson's Baby Powder and Shower to Shower?</p> <p>15 A. Do I try to answer it again?</p> <p>16 MS. SHARKO: Yes. Do you know what the 17 constituents are? Besides talc, I assume.</p> <p>18 THE WITNESS: I don't work for Johnson & 19 Johnson. I don't know exactly what's in their products.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. And do you know what the alleged contaminants are in 22 Johnson & Johnson and Shower to Shower?</p> <p>23 MS. SHARKO: I object to the form of the 24 question.</p> <p>25 THE WITNESS: I guess what has been reported.</p>

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<p style="text-align: right;">Page 46</p> <p>1 I mean, from the articles I read, I don't -- so you see 2 in my report I -- I have -- I discuss a lot about work 3 done by Saed, who utilizes Johnson & Johnson's Baby 4 Powder. He doesn't go into detail about the 5 constituents of Johnson & Johnson Baby Powder, however, 6 he utilizes it for all of his experiments. And again, I 7 do a deep dive and assessment of all the experiments in 8 those -- in that research, and I do not see evidence of 9 a mechanistic impact of Johnson & Johnson's Baby Powder 10 on ovarian cancer cells. That's all I can say about 11 that.</p> <p>12 MS. THOMPSON: And again, I'll object to the 13 answer as non-responsive and certainly didn't ask 14 anything at this point about Dr. Saed.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Do you know what the alleged contaminants are in 17 Johnson's Baby Powder and Shower to Shower?</p> <p>18 MS. SHARKO: Well, I'm going to object at this 19 point. This is the third time you've asked this 20 question. Dr. DiFeo has given a detailed response. And 21 if you don't think the answer is responsive to your 22 question, I respectfully suggest that you rephrase the 23 question. It sounds to me, if I may, like you're asking 24 her if she knows what the plaintiffs' allegations are.</p> <p>25 MS. THOMPSON: Well, she, at least has on her</p>	<p style="text-align: right;">Page 48</p> <p>1 were performed using the Johnson & Johnson Baby Powder. 2 However, in the studies that I analyzed that were 3 performed using Johnson & Johnson Baby Powder, I 4 didn't -- there was no evidence that that baby powder 5 contributed or had a functional role on ovarian cancer 6 pathogenesis.</p> <p>7 Q. The next sentence in that paragraph on Summary of 8 Opinions specifically -- do you see where I'm reading? 9 Second sentence?</p> <p>10 A. Remind me. Sorry. I forget where we were.</p> <p>11 MS. SHARKO: (Indicating.)</p> <p>12 THE WITNESS: Okay.</p> <p>13 BY MS. THOMPSON:</p> <p>14 Q. Summary of Opinions, page 6.</p> <p>15 A. Um-hum (affirmatively).</p> <p>16 Q. Specifically cosmetic talc has not been shown to be 17 capable of migrating to the fimbrial end of the 18 fallopian tubes from which most ovarian cancers arise. 19 Did you do a thorough review of whether or not 20 substances, including particles, can migrate from the 21 external environment to the tubes, ovaries, and 22 peritoneal cavity?</p> <p>23 A. Yeah. So I believe my report I have some studies in 24 primates that I reference that tried to perform very 25 extensive studies and non-physiological studies, trying</p>
<p style="text-align: right;">Page 47</p> <p>1 materials, reviewed and considered all the plaintiffs' 2 expert reports.</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Are you aware that the plaintiffs are alleging that 5 Johnson's Baby Powder and Shower to Shower contain 6 asbestos and talc fibers?</p> <p>7 A. So I -- again, I said I didn't read -- I did not read 8 all the plaintiffs' reports. It's -- I'm not a lawyer, 9 I don't spend the time reading plaintiff -- I'm a 10 scientist. I go through data, experiments, 11 understanding ovarian cancer. I did not -- I didn't 12 see -- you asked me in the way beginning what keywords I 13 searched. And in the keywords when I searched talc and 14 ovarian cancer, I did not see data on that -- exactly 15 what you just mentioned. So maybe that's why I couldn't 16 answer your -- I didn't find that and I couldn't answer 17 that.</p> <p>18 Q. Okay. If Johnson's Baby Powder and Shower to Shower 19 contained asbestos and talc fibers, would that influence 20 your opinions in this case at all?</p> <p>21 A. No. Because -- I think I mentioned it before. If it 22 did, then the experiments that were run using the 23 Johnson & Johnson Baby Powder and individuals believe 24 that that had contributed to ovarian cancer, then we 25 would have seen different results in the studies that</p>	<p style="text-align: right;">Page 49</p> <p>1 to administer talc intravaginally and somewhat 2 aggressively in primates and look at whether talc was 3 found in the fimbriated end of the fallopian tube, and 4 also some rat studies, so I did review that, and 5 included that in my report.</p> <p>6 Q. And we'll talk about those in a few minutes. 7 Were the animal studies regarding migration 8 more important to your understanding of this issue than 9 the human studies, of which there are many?</p> <p>10 MS. SHARKO: Object to the form of the 11 question.</p> <p>12 You can answer.</p> <p>13 THE WITNESS: Sorry, I want -- it's hard for 14 me to answer the question without references or pulling 15 up human studies that looked at migration of talc to the 16 fallopian tube.</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. And I think my original question was, did you do a 19 comprehensive review of the issue?</p> <p>20 A. Sorry, can you -- what was -- I thought you -- can you 21 repeat the question?</p> <p>22 Q. Did you do a comprehensive review of the literature 23 regarding whether substances, including talc, can ascend 24 the reproductive tract to reach the tubes?</p> <p>25 MS. SHARKO: Objection, asked and answered.</p>

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<p style="text-align: right;">Page 50</p> <p>1 THE WITNESS: So I think I just answered that 2 question before. And -- yeah. And I mentioned that I 3 included those references in the report.</p> <p>4 BY MS. THOMPSON:</p> <p>5 Q. Okay. We'll get to those. And we'll also get to more 6 of the rest of the summary, including the malignant 7 transformation.</p> <p>8 I'd like to understand when you use a term, a 9 phrase, or a word, exactly what it means to you. So I'm 10 going to see if I can pin that down a little bit. If we 11 could. What do you consider a risk factor when thinking 12 about what might be in-- let me start all over with that 13 question.</p> <p>14 How would you define a risk factor? And this 15 is specifically for ovarian cancer.</p> <p>16 A. So a risk factor would be something that when an 17 individual's exposed to it for a certain amount of time 18 or, whether it be a substance or a genetic factor, that 19 there's enough plausible evidence that it contributes --</p> <p>20 Q. I'm sorry, did you say plausible evidence?</p> <p>21 A. Plausible evidence, yes.</p> <p>22 Q. I'm sorry, I didn't hear the words.</p> <p>23 A. That it contributes to the -- sorry. That it 24 contributes to the onset of their disease.</p> <p>25 Q. So if I'm understanding you correctly, it would be an</p>	<p style="text-align: right;">Page 52</p> <p>1 the disease pathogenesis and ovarian cancer 2 pathogenesis.</p> <p>3 Q. So let me make sure I'm understanding you, and correct 4 me if I'm not.</p> <p>5 Are contributing to and causing equivalent 6 when you use those two words?</p> <p>7 A. It's -- again, I think I -- it's how -- I would say no. 8 But again, it depends on the scientist. Contributing, 9 to me, seems like more of a soft word, just like 10 association. Causing is a more definitive word. You 11 actually have a mechanism, and I would say it's driving 12 the disease. It is a functional role and impact. And 13 then with -- so a lot of times in research we say, is it 14 necessary or sufficient. And that's what I think is 15 critical when we're thinking about cancer pathogenesis. 16 And why we need to know that is, if we're truly trying 17 to understand whether something's a biomarker or a drug 18 target, we need to know whether it's required and 19 necessary for cancer development. Because if you're 20 going to target it or use it as a biomarker, you need to 21 know whether it's driving the disease.</p> <p>22 Q. And this is an important concept for me to understand, 23 and I'm not trying to ask a repetitive question, but I 24 do want to make sure I understand the difference in your 25 opinions. So am I understanding correctly that</p>
<p style="text-align: right;">Page 51</p> <p>1 association, along with a plausible mechanism, is that 2 fair?</p> <p>3 A. Yes.</p> <p>4 Q. And when you describe something as contributing to the 5 development, would that be similar to a risk factor in 6 terms of definition?</p> <p>7 A. The word contributing is somewhat vague and broad. 8 People use that word quite often, but something could 9 contribute, but not be functionally validated or 10 impactful. So I believe in science there's many 11 criteria that we need to determine prior to saying 12 the -- or solidifying the contribution of a factor in 13 disease relevance.</p> <p>14 For example, whether it's reproducible across 15 various assays, whether it's dose and time dependent. I 16 think many people refer to this, for instance, as the 17 Bradford Hill criteria. Whether it precedes the 18 disease. There's numerous criteria that needs to be 19 accomplished prior to determining whether a factor is 20 actually meaningful and causative. And I will tell you 21 that this is literally the foundation of my lab because 22 there's many associations with cancer, specifically 23 ovarian cancer, however, these associations need to be 24 validated in order to determine their impact and whether 25 they're truly driving the outcomes and contributing to</p>	<p style="text-align: right;">Page 53</p> <p>1 contribution -- contributing is more an association and 2 cause would be a higher bar that requires a plausible 3 mechanism? Is that fair?</p> <p>4 A. Yeah, I would agree with that.</p> <p>5 Q. Okay. Because I am trying -- I wasn't -- again, that 6 was just an example. I wasn't trying to ask you a trick 7 question, I was just trying to make sure I understand 8 what you were saying.</p> <p>9 A. If I can just elaborate a little bit more. Cancer is a 10 complex disease. If we -- if it was just one thing that 11 contributed, we would have a cure. And that's why I say 12 contribution is one aspect. If -- there's multiple 13 things that contribute to it. And that's why we have to 14 understand what causes it. So there can be 50 things 15 that contribute to it, but only five that cause it, if 16 that helps explain it more clearly. And that's what we 17 need to get to.</p> <p>18 Q. And so it's your opinion that the genital application of 19 talc, let me use your exact word, is not one of those 20 many contributors, or cannot be one of those 21 contributors?</p> <p>22 A. No. Because even -- if it was, then you would see 23 some -- if it was a contributing factor, you would see 24 that -- with low dose or some aspects of it that you 25 would -- it would participate in the pathogenesis of</p>

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<p style="text-align: right;">Page 54</p> <p>1 ovarian cancer.</p> <p>2 Q. Okay. When you use the word hypothesis, explain to me</p> <p>3 what that means to Dr. DiFeo.</p> <p>4 A. So hypothesis is an educated guess, based on preliminary</p> <p>5 data. And you have a strong rationale to support that</p> <p>6 hypothesis.</p> <p>7 Q. Can hypothesis and plausible be used interchangeably?</p> <p>8 A. No, I -- no.</p> <p>9 Q. What would be the difference between a hypothesis and a</p> <p>10 plausible mechanism?</p> <p>11 A. I mean, I don't know -- can you -- what -- I don't</p> <p>12 understand the question. I'm sorry.</p> <p>13 Q. Okay. It may not have been -- no, that's --</p> <p>14 A. I'm just trying to -- I'm trying to understand</p> <p>15 exactly -- I -- sorry, in my field, I'm trying to -- so</p> <p>16 hypothesis is typically what we use when we're trying to</p> <p>17 make an educated guess, like I said, the preliminary</p> <p>18 data that we generate or that we assess from the</p> <p>19 literature. But plausible, I don't -- I don't know in</p> <p>20 reference to what. That's not usually -- I would never</p> <p>21 put the two together, so I'm trying to understand your</p> <p>22 question.</p> <p>23 Q. And that's what you're supposed to be doing when you</p> <p>24 don't understand a question, and so let me see if I can</p> <p>25 ask it differently.</p>	<p style="text-align: right;">Page 55</p> <p>1 Let's put a hypothesis in terms of a</p> <p>2 hypothetical mechanism, okay?</p> <p>3 A. Okay. That makes it a little easier.</p> <p>4 Q. And relate that to a plausible mechanism. Would those</p> <p>5 be different in your mind?</p> <p>6 A. Okay. That makes a little bit more sense, sure.</p> <p>7 Q. Agreed.</p> <p>8 A. Yeah. That one I get. Before, I didn't get it. Okay.</p> <p>9 Yeah. That makes sense. Okay. They're -- that's more</p> <p>10 similar, yeah.</p> <p>11 Q. You wouldn't -- if you had a hierarchy, you wouldn't</p> <p>12 place one as more rigorous than the other?</p> <p>13 A. Yeah. I guess, it's all -- those are just terms. In</p> <p>14 the end, it's -- the rigor comes from where that</p> <p>15 hypothesis or plausible mechanism is based on, what data</p> <p>16 it's based on. It's all based on the experimental data,</p> <p>17 the rigor that that data's based on, the reproducibility</p> <p>18 of that data. That's research, that's science.</p> <p>19 Q. Understood. Thank you.</p> <p>20 MS. THOMPSON: Would this be a good time for a</p> <p>21 break?</p> <p>22 A. Yes.</p> <p>23 MS. SHARKO: Sure.</p> <p>24 (A short recess was taken)</p> <p>25 BY MS. THOMPSON:</p>	<p style="text-align: right;">Page 56</p> <p>1 Q. Okay. Dr. DiFeo, what is your understanding of the</p> <p>2 process for determining causation or making a causal</p> <p>3 inference in epidemiology?</p> <p>4 A. So as I mentioned before, I work and collaborate with a</p> <p>5 lot of epidemiologists, given that my expertise is in</p> <p>6 cancer biology, so I don't feel comfortable really</p> <p>7 getting into the specifics about epidemiology.</p> <p>8 Q. What is the process, or do you know the process of</p> <p>9 determining causation in the epidemiology field?</p> <p>10 A. Are you asking --</p> <p>11 MS. SHARKO: Object to the form of the</p> <p>12 question.</p> <p>13 THE WITNESS: I don't -- are you asking once</p> <p>14 there's an association based on epidemiological studies,</p> <p>15 how do we show that that association is actually</p> <p>16 causative?</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. Yes.</p> <p>19 A. Oh. So various association studies have been done for</p> <p>20 various things, such as talc and many of them have</p> <p>21 contradicted each other. Therefore, the next step is to</p> <p>22 then determine whether that association, given the</p> <p>23 contradiction, is actually playing a functional role or</p> <p>24 mechanistic role in disease. There's numerous steps</p> <p>25 that need to be kind of accomplished to determine the</p>
		<p style="text-align: right;">Page 57</p> <p>1 causal role in the pathogenesis of disease, such as</p> <p>2 ovarian cancer. And I mentioned before, I know one</p> <p>3 thing that many people speak about is Bradford Hill.</p> <p>4 It's not a common term that we use as biologists or</p> <p>5 cancer biologists. But the criteria is very similar.</p> <p>6 And the criteria is, it includes, not limited to, that</p> <p>7 the substance precedes the disease. There's a</p> <p>8 dose-dependent effect that the more exposure, let's say,</p> <p>9 then induces a more -- stronger mechanistic impact on</p> <p>10 the disease progression. There is a temporal effect, so</p> <p>11 the longer you're exposed to that or the cells are</p> <p>12 exposed to that reagent, the stronger the implications</p> <p>13 are or the transformative effects are on those cells.</p> <p>14 The reproducibility of those effects. So numerous</p> <p>15 people can reproduce the data, or it's reproduced in a</p> <p>16 number of independent patient cell lines. And relevant</p> <p>17 patient cell lines or models. So that's just to give</p> <p>18 you a few examples of how you would validate</p> <p>19 epidemiological studies.</p> <p>20 Q. Did you do a Bradford Hill analysis?</p> <p>21 A. So I just mentioned, so that's -- that's the criteria I</p> <p>22 just mentioned, and that's what I restated, those are</p> <p>23 some of the criteria that are used for the Bradford Hill</p> <p>24 analysis.</p> <p>25 And when I state in my report the</p>

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<p style="text-align: right;">Page 58</p> <p>1 transformation, when we think about transformation, a 2 lot of that is, essentially, what Bradford Hill is, 3 right? You need to have certain mechanisms to occur for 4 transformation. And if you think of cancer progression, 5 it's the same concept. You need multiple mutations to 6 occur, number one. You need uncontrolled proliferation 7 to occur, number two. There's -- you need an 8 antiapoptotic effect, number three. You need cells to 9 grow in anchorage-independent growth, right? So there's 10 numerous steps that we know and criteria that need to be 11 fulfilled in order for transformation to be 12 accomplished.</p> <p>13 Q. And I'll object to the answer as non-responsive. 14 My question was, did you perform a Bradford 15 Hill analysis?</p> <p>16 A. So when you mention did I perform a Bradford Hill 17 analysis, as I'm reading papers on -- all the top 18 papers, it's -- the Bradford Hill analysis is, 19 essentially, an analysis that, as a researcher, as a 20 scientist, we do subconsciously when we're thinking 21 about causation. These are things that are innate in us 22 because --</p> <p>23 Q. So the answer is --</p> <p>24 A. Yes. I did. Yes, I did.</p> <p>25 Q. Where would I find that in your report?</p>	<p style="text-align: right;">Page 60</p> <p>1 assessment of whether talc plays a role in ovarian 2 cancer transformation. Was that your question? 3 BY MS. THOMPSON: 4 Q. Well, my question wasn't understanding, my question was 5 the demonstration of malignant transformation critical 6 to your opinion? 7 A. Oh, yes. Yes. 8 Q. Okay. I want to look at some literature regarding the 9 determination of causality. And some of this may not be 10 on your reliance, but I think it's important, 11 nonetheless.</p> <p>12 MS. THOMPSON: Laura, if we could pull Rothman 13 article titled Causation and Causal Inference in 14 Epidemiology. And let's mark that as Exhibit 6.</p> <p>15 DEPOSITION EXHIBIT 6 16 Kenneth Rothman Article - Causation 17 and Causal Inference Epidemiology 18 WAS MARKED BY THE REPORTER 19 FOR IDENTIFICATION</p> <p>20 BY MS. THOMPSON: 21 Q. Okay. And if I'm asking you about an article that you 22 haven't seen before, you're entitled to look over that 23 article. If you need any extended time to look at it, 24 that's fine, too, but we'll go off the record in that 25 case, fair?</p>
<p style="text-align: right;">Page 59</p> <p>1 A. So we don't -- if you look at many of the research 2 articles by medical scientists published, we don't use 3 the term Bradford Hill. So I don't typically use that 4 term. And that's why I was mentioning the 5 transformation. It's intertwined in those assays. So 6 though I may not say the word Bradford Hill, it's a 7 common concept in research.</p> <p>8 Q. If you'll turn to page 17 of your report when you 9 discuss malignant transformation, Section 8.</p> <p>10 A. Yes.</p> <p>11 Q. Is -- beginning with progression of a normal -- no. Let 12 me ask that again.</p> <p>13 Was the demonstration of malignant 14 transformation critical to your opinion that talc does 15 not contribute or cause ovarian cancer?</p> <p>16 A. Sorry, where is that on page 17?</p> <p>17 Q. I'm just asking the question. We're going to the page 18 later. I shouldn't have directed you.</p> <p>19 MS. SHARKO: Could you just rephrase --</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. Was the demonstration of malignant transformation 22 critical to your opinion that talc does not contribute 23 to or cause ovarian cancer?</p> <p>24 A. So yes, so the -- criteria -- understanding how 25 malignant transformation occurs was critical in my</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Yes.</p> <p>2 Q. And I'm going to direct you to the area of this article 3 that I want to specifically address and ask you if you 4 agree.</p> <p>5 Have you heard the name Kenneth Rothman or 6 Sander Greenland?</p> <p>7 MS. SHARKO: Do you want to give Dr. DiFeo --</p> <p>8 THE WITNESS: I haven't seen -- I haven't seen 9 this paper before, so I kind of want to get a little 10 acquainted with this. This is not -- I'm not familiar 11 with this manuscript.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. Well, let me ask you the questions, and if you need time 14 to read the whole paper to answer the questions, we can 15 go off the record, okay?</p> <p>16 A. Um-hum (affirmatively). Sure. Yes.</p> <p>17 Q. Are you familiar with the names Kenneth Rothman and 18 Sander Greenland?</p> <p>19 A. Yeah. I've heard their name before. But again, I'm 20 not -- this is not a paper I've read before or reviewed.</p> <p>21 Q. Fair. And would that -- have you heard their names?</p> <p>22 Because Dr. Rothman in particular, a well-recognized 23 name in epidemiology, for example, has written the 24 textbook typically regarding epidemiology.</p> <p>25 A. I'm not sure. I think, as I mentioned, there's a lot of</p>

<p style="text-align: right;">Page 62</p> <p>1 my colleagues, colleagues of mine that are 2 epidemiologists that I collaborate with extensively. I 3 go to numerous conferences and, you know, could be 4 exactly -- maybe I heard it in the field. So I don't 5 remember why, but I'm familiar.</p> <p>6 Q. And Dr. Rothman's expert report for the plaintiffs was 7 in your materials considered and relied on, are you 8 aware of that?</p> <p>9 A. I'm not -- I don't remember. But maybe that's -- I 10 can't say. It's also a very common last name.</p> <p>11 Q. Okay. Well, let's just see what Dr. Rothman says about 12 causation. If you look at the first page, the beginning 13 of the third paragraph -- sorry, beginning of the third 14 column. Drs. Rothman and Greenland state: In other 15 words, the cause of a disease event is an event, 16 condition, or characteristic that preceded the disease 17 event and without which disease event either would not 18 have occurred at all or would not have occurred until 19 some later time.</p> <p>20 Do you think that definition, it may be that 21 no specific event, condition, or characteristic is 22 sufficient by itself to produce disease? Would you 23 agree with Dr. Rothman's statement there?</p> <p>24 A. So, again, this -- number one, I've never seen this 25 manuscript. Number two, epidemiology is not my area of</p>	<p style="text-align: right;">Page 64</p> <p>1 Q. And did you utilize Dr. Rothman's methodology as 2 described in this article to formulate your opinion that 3 talc does not contribute to or cause ovarian cancer?</p> <p>4 A. So a lot of what he states here is more -- again, I 5 think mentioning Bradford Hill and his opinion on how we 6 can assess or interpret epidemiological studies.</p> <p>7 The methodology I utilized was based on 8 reviewing the literature and the scientific studies that 9 were performed, actually, according to the Bradford Hill 10 criteria. So they performed experiments looking at 11 exactly as delineated in this manuscript. All right.</p> <p>12 So they looked at the strength, the specificity, the 13 consistency, the temporal effects of talc. So yes, I 14 did.</p> <p>15 Q. But to be fair, you did not include any epidemiological 16 study in your reports, correct?</p> <p>17 A. I did not. However, when I mention I utilize Bradford 18 Hill, it's more on the causal and mechanistic role of 19 talc.</p> <p>20 Q. So would it be fair to say that that would only be in 21 the Bradford Hill factor regarding biological 22 plausibility?</p> <p>23 A. I would disagree just to say -- because when we talk 24 about biological plausibility, I think it would also cover the temporal. Because when they mentioned</p>
<p style="text-align: right;">Page 63</p> <p>1 expertise. I do not feel comfortable agreeing or 2 disagreeing with your comment based on the two minutes 3 that I've had to read this. I like to do thorough 4 assessments when asked a question, especially if it's 5 not my area of expertise, and it's a very vague --</p> <p>6 Q. But you are aware --</p> <p>7 A. It's a very vague statement. But I would -- under 8 this -- so you're mentioning, under this definition it 9 may be that no specific event, condition, or 10 characteristic is sufficient by itself to produce 11 disease. I mean, it's, again, a very vague statement.</p> <p>12 MS. SHARKO: Margaret, if you're going to go 13 into this paper, I think it's only fair to give 14 Dr. DiFeo time to read it.</p> <p>15 THE WITNESS: Yeah, I would --</p> <p>16 MS. THOMPSON: Okay. Let's go off the record. 17 Let me when know when you feel like you have looked at 18 this paper sufficiently.</p> <p>19 (A short recess was taken)</p> <p>20 THE WITNESS: Okay.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Dr. DiFeo, did you have a chance to read the paper by 23 Drs. Rothman and Greenland titled Causation and Causal 24 Inference in Epidemiology?</p> <p>25 A. Yeah. I've read most of it, yeah.</p>	<p style="text-align: right;">Page 65</p> <p>1 temporal, that -- the studies that we're looking at, 2 right, if we were looking in primates, mice, you could 3 assess that there as well. Or dose dependency or 4 specificity or reproducibility or consistency. So you 5 could look at that when you look at association studies, 6 but you also look at that when you're looking at 7 biological studies or reproducibility.</p> <p>8 Q. But my question was, did you follow this methodology 9 outlined in this paper?</p> <p>10 A. So this paper specifically looks at epidemiology. So I 11 guess in terms of the epidemiological aspect of it, no.</p> <p>12 Q. Dr. Rothman, if you'll turn to page 145 of his paper, 13 it's after the second page. Dr. Rothman states under 14 the heading Multicausality, first paragraph: A given 15 disease can be caused by more than one causal mechanism, 16 and every causal mechanism involves the joint action of 17 a multitude of component causes.</p> <p>18 Do you agree with that statement?</p> <p>19 A. Yes.</p> <p>20 Q. Is it your opinion that genetic mutations are the only 21 cause of ovarian cancer?</p> <p>22 A. Yes.</p> <p>23 Q. Let's look at the second paragraph, the second column, 24 first full paragraph of Dr. Rothman's paper.</p> <p>25 Dr. Rothman states: The importance of multicausality is</p>

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<p style="text-align: right;">Page 66</p> <p>1 that most identified causes are neither necessary, nor 2 sufficient to produce disease. Nevertheless, a cause 3 need not be either necessary or sufficient for its 4 removal to result in disease prevention. If a component 5 cause that is neither necessary nor sufficient is lost, 6 a substantial amount of disease may be prevented. 7 Do you agree that statement?</p> <p>8 A. No. I mean, it is really -- it's dependent on, this is 9 such a broad statement, it's so dependent on what 10 disease you're talking about. We're talking about 11 cancer and what type of cancer. You can -- I don't -- 12 it's too broad for me to agree with that statement.</p> <p>13 Q. But Dr. Rothman is in this paper addressing how to 14 establish causality in a wide range of situations, 15 correct?</p> <p>16 A. Again, I can't speak for Dr. Rothman. But again, it's a 17 very broad statement. My expertise is in cancer. And I 18 could not make -- I would not agree with that statement 19 if we're speaking about cancer, or ovarian cancer.</p> <p>20 Q. Would that be because, in your opinion, multicausality 21 does not apply to ovarian cancer?</p> <p>22 A. No. I think, unfortunately, we don't know all of the 23 causes of ovarian cancer and all of the genetic factors 24 that contribute to ovarian cancer. If we did, we would 25 have a cure or better preventative methods or biomarkers</p>	<p style="text-align: right;">Page 68</p> <p>1 Q. Okay -- 2 A. No, aging is one of the risk factors, yes. 3 Q. But is it a cause, is my question. 4 A. It is a risk factor for ovarian cancer. It is -- it 5 can -- I mean, when you mention -- it itself is not 6 sufficient, but because that alone -- like I said, 7 there's multiple -- and it -- there's multiple causes. 8 If there's underlying germline mutations -- so, for 9 instance, if an individual has genetic predispositions, 10 right, so if they have BRCA mutations or other genetic 11 alterations that they're born with, then aging on top of 12 that could also contribute to ovarian cancer. So -- 13 Q. Okay. Let's get back to -- 14 A. -- I would define it as yes, it is a cause. 15 MS. SHARKO: Wait. Let Dr. DiFeo finish. 16 THE WITNESS: Sorry. 17 MS. SHARKO: Go on. 18 THE WITNESS: So yes, age is a cause as well. 19 Yeah. And, actually, that's why we say why the 20 incidence of cancer has increased is because, luckily, 21 our healthcare system has improved and people are living 22 longer. That's why -- 23 BY MS. THOMPSON: 24 Q. Let's go back -- 25 MS. SHARKO: Wait, wait, wait. Dr. DiFeo was</p>
<p style="text-align: right;">Page 67</p> <p>1 to detect it earlier and we'd know how to prevent it. 2 So I cannot agree with that statement. But what I do 3 know, ovarian cancer is a genetic disease, and it takes 4 several various mutations to occur in key genes that 5 regulate proliferation, apoptosis, and digenesis that 6 then convert a normal cell to a tumor.</p> <p>7 Q. And is it your opinion that anything that contributes to 8 those gene mutations is not a cause?</p> <p>9 A. I'm sorry, can you repeat that question?</p> <p>10 Q. Okay. So your opinion that genetic mutations are the 11 only cause for ovarian cancer, correct?</p> <p>12 A. Genetic mutations, yes, cancer is a genetic disease, 13 yes.</p> <p>14 Q. And so some things that contribute to those mutations, 15 for example, age.</p> <p>16 A. Yes, perfect. Yep.</p> <p>17 Q. Is not a cause of ovarian cancer?</p> <p>18 A. Yes, it is. Age is a cause of ovarian cancer.</p> <p>19 Q. Okay.</p> <p>20 A. Because age contributes to mutations. As we age, the 21 proofreading genes that were necessary to repair our DNA 22 and telomerase, which is essential, right, for 23 proliferation, are decreased. I mean, that's why those 24 are part of the anti-aging drugs that people try to 25 take, yes.</p>	<p style="text-align: right;">Page 69</p> <p>1 still talking.</p> <p>2 THE WITNESS: So many times when people ask 3 me, oh, why has incidence of cancer increased, sometimes 4 one of the answers is we live longer. So age is a 5 cause. Sorry. Just to answer your question.</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. All right. Let's go back to -- are you finished?</p> <p>8 A. Yes, now I'm done.</p> <p>9 Q. Let's go back to your opinion in this case. And let's 10 substitute age for cosmetic talc. And would you agree 11 with the statement that age can cause or contribute to 12 the development of ovarian cancer?</p> <p>13 A. Yes.</p> <p>14 Q. Would you agree with that?</p> <p>15 A. Yes.</p> <p>16 Q. And you would also agree to BRCA and other germline 17 mutations can cause or contribute to the development of 18 ovarian cancer?</p> <p>19 A. Germline -- yes.</p> <p>20 Q. Would you make the statement that endometriosis can 21 cause or contribute to development of ovarian cancer?</p> <p>22 A. Yes.</p> <p>23 Q. Would you make the statement that obesity can cause or 24 contribute to the development of non-serous ovarian 25 cancer?</p>

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<p style="text-align: right;">Page 70</p> <p>1 A. Okay, non-serous, yes. There's some data to support 2 that.</p> <p>3 Q. Would you be able to state that smoking can cause or 4 contribute to the development of mucinous ovarian 5 cancer?</p> <p>6 A. I'm not -- the mechanistic -- I'm not as well-versed on 7 the role of smoking in mucinous. No, I don't know. I'm 8 not confident in that statement, no.</p> <p>9 Q. Would you agree with the statement, nulliparity can 10 cause or contribute to the development of ovarian 11 cancer?</p> <p>12 A. That is true, yes. That is a risk factor, contributes, 13 yeah.</p> <p>14 Q. Would you agree to asbestos exposure could cause or 15 contribute to the development of ovarian cancer?</p> <p>16 A. No, I have not seen any evidence of that.</p> <p>17 Q. Have you seen IARC's -- what is IARC?</p> <p>18 A. I believe it's something to the World Health 19 Organization, it's an international organization, or a 20 regulatory organization.</p> <p>21 Q. Are you aware that IARC has determined that asbestos can 22 cause ovarian cancer?</p> <p>23 A. So I'm not as familiar with how they determine their 24 recommendations or, you know, I don't know if that's 25 based on association studies or mechanistic studies,</p>	<p style="text-align: right;">Page 72</p> <p>1 but unfortunately, don't have mutations and the known 2 genes that predispose them to breast or ovarian cancer, 3 and we're still trying to uncover those unknown genes.</p> <p>4 Q. Would you agree -- could you substitute postmenopausal 5 hormone replacement can cause or contribute to the 6 development of ovarian cancer?</p> <p>7 A. No, I don't have -- there's -- my opinion, there's not 8 enough data to conclusively agree with that.</p> <p>9 Q. But you do have the data you need to determine that 10 talcum powder use does not cause or contribute to 11 development of ovarian cancer, correct?</p> <p>12 A. Yes.</p> <p>13 Q. You know that others would disagree with you, other 14 scientists and researchers?</p> <p>15 A. I guess -- I don't -- I don't commonly -- so like I 16 said, I work in this field extensively, I go to numerous 17 conferences. It doesn't actually come up in many 18 conferences. And negative data's rarely published, so I 19 don't -- I can't speak to what other people believe, but 20 it's -- the mechanistic role of talc in ovarian cancer 21 pathogenesis has not been shown, so I don't know. All I 22 know is my opinion and I've stated it here many times.</p> <p>23 Q. Well, you've -- sorry, are you finished?</p> <p>24 A. Yeah.</p> <p>25 Q. You reviewed the literature, correct?</p>
<p style="text-align: right;">Page 71</p> <p>1 that's not something I commonly read, but I know I read 2 it through these conversations and doing some research 3 through these reports -- for this report through talc.</p> <p>4 Q. Would you be able to substitute family history can cause 5 or contribute to ovarian cancer, the development of 6 ovarian answer?</p> <p>7 A. Yeah, depending on which cancers the family members 8 have. And if --</p> <p>9 Q. If there's a family history of breast, ovarian, or 10 colon --</p> <p>11 A. Breast, ovarian --</p> <p>12 Q. -- would you say that --</p> <p>13 A. Sorry, go ahead.</p> <p>14 Q. Let me finish the question.</p> <p>15 Could you substitute a family history of 16 breast, ovarian, or colon cancer in a first-degree 17 relative can cause or contribute to the development of 18 ovarian cancer?</p> <p>19 A. Yes, depending on what degree, but yes, potentially.</p> <p>20 Q. And that would be true even if there were no genetic 21 mutations discovered on testing?</p> <p>22 A. Yes. And unfortunately, we don't know all the germline 23 mutations that cause ovarian cancer. And, actually, 24 that's what I was studying. So there's large families 25 that we know of that have clear genetic predispositions;</p>	<p style="text-align: right;">Page 73</p> <p>1 A. Yes.</p> <p>2 Q. You don't have to talk to the authors to understand that 3 they are of the opinion that talcum powder use can cause 4 ovarian cancer -- can cause or contribute to the 5 development of ovarian cancer, do you?</p> <p>6 A. I interpret it as it's associated. An association, to 7 me, doesn't tell me it's causal. And, actually -- and I 8 mention it also in the O'Brien, and that's why I amended 9 my report to include the O'Brien paper. Because even in 10 the most recent association study, they mention that 11 there may be an association, but the causation and the 12 mechanistic impact of it is unclear and unknown.</p> <p>13 Q. Well, I didn't ask you about O'Brien. I will ask 14 O'Brien later. But O'Brien, in all fairness, did not do 15 a causation analysis, correct?</p> <p>16 A. No. But you mentioned other authors that suggested that 17 talc was associated or cause of ovarian cancer, and 18 that's one of the studies that suggested that it was 19 associated, that's why I mentioned it.</p> <p>20 Q. Do O'Brien and the other authors say that talc does not 21 contribute to the development of ovarian cancer?</p> <p>22 A. I don't have that paper in front of me, I don't remember 23 exactly the words they said.</p> <p>24 Q. Okay. We can look at it when you have the paper in 25 front of you.</p>

<p style="text-align: right;">Page 74</p> <p>1 Do O'Brien and the other authors state that 2 there is no plausible mechanism by which talc powder 3 could cause or contribute to ovarian cancer?</p> <p>4 A. Yeah, I think that's what I stated with the O'Brien 5 paper. They do explicitly say there's no mechanism, 6 yes. There's no known mechanism.</p> <p>7 Q. Do they say there's no plausible mechanism?</p> <p>8 A. I don't know exactly verbatim what they state. I think 9 we could pull up my report, I think I do include a quote 10 from their manuscript.</p> <p>11 Q. So back to my original question. You are aware that 12 there are numerous papers and authors that state clearly 13 that talcum powder use contributes to the development of 14 ovarian cancer, or are you not aware of any of the 15 papers to that effect?</p> <p>16 MS. SHARKO: Object to the form of the 17 question.</p> <p>18 THE WITNESS: I am aware of the papers that 19 have stated that.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. Let's move on to another paper that relates to 22 determination of causality.</p> <p>23 MS. THOMPSON: Laura, if you could pull the 24 Smith paper, titled Key Characteristics of Carcinogens.</p> <p>25 DEPOSITION EXHIBIT 7</p>	<p style="text-align: right;">Page 76</p> <p>1 MS. THOMPSON: Okay. Let's go off the record 2 and give you a chance to read it. And I would say we're 3 going to look primarily at the key characteristics of 4 carcinogens that are included on the chart on the second 5 page, but I'll give you a chance to read through it. 6 Off the record.</p> <p>7 (A short recess was taken)</p> <p>8 THE WITNESS: Okay. I'm ready.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. Okay. Would you agree that this paper describes the 11 IARC, the International Agency for Research on 12 Carcinogens, methodology by which that organization 13 determines that a substance is carcinogenic?</p> <p>14 A. Yes. I mean, yes. It seems that way, yes.</p> <p>15 Q. And --</p> <p>16 A. Well, I would say --</p> <p>17 MS. SHARKO: Wait, wait, wait.</p> <p>18 THE WITNESS: I just want to be clear here. I 19 don't see all the supplemental data. I was trying to 20 look for what substances did they test.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Right now we're talking about the methodology that they 23 used.</p> <p>24 A. Okay. Okay. That was one thing I couldn't figure out 25 from this paper. Okay.</p>
<p style="text-align: right;">Page 75</p> <p>1 Martyn Smith Paper - Key 2 Characteristics of Carcinogens 3 WAS MARKED BY THE REPORTER 4 FOR IDENTIFICATION</p> <p>5 BY MS. THOMPSON:</p> <p>6 Q. Do you have that?</p> <p>7 A. Yes, I have it.</p> <p>8 Q. Have you seen this article before, Dr. DiFeo?</p> <p>9 A. No, I have not seen this.</p> <p>10 Q. Do you need a few minutes to look at it?</p> <p>11 A. Yeah. I have not seen this before.</p> <p>12 Q. I can direct you to the pages to answer questions. But 13 if you want more time, we'll go off the record.</p> <p>14 A. If I could just skim it to see -- or do you want to just 15 ask me the question and see if --</p> <p>16 Q. Okay. So this paper sets forth the methodology that the 17 International Agency for Research in Carcinogens uses 18 would determine whether something is carcinogenic, would 19 you agree?</p> <p>20 MS. SHARKO: Wait. I object to the form of 21 the question. For that you're going to have to let the 22 doctor read the paper.</p> <p>23 THE WITNESS: Yeah, that kind of question -- I 24 mean, you literally asked me what the paper's about; and 25 that, I would need to read the paper.</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. Okay. And in the abstract under Conclusion, the authors 2 of this paper state: We describe the use of the ten key 3 characteristics to conduct a systematic literature 4 search focused on relevant endpoints and construct a 5 graphical representation of the identified mechanistic 6 information.</p> <p>7 And that referred specifically to the 8 identification of carcinogen, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And then the end of that, the authors state: The 11 approach described is similar in many respects to those 12 currently being implemented by the U.S. EPA's Integrated 13 Risk Information System Program and the U.S. National 14 Toxicology Program.</p> <p>15 Did I read that correctly from this article?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. In the introduction, second column, the paper 18 states: Many human carcinogens act via multiple 19 mechanisms causing various biological changes in the 20 multistage process of carcinogenesis.</p> <p>21 Do you agree with that statement?</p> <p>22 A. Yes.</p> <p>23 Q. If you go to the Key Characteristics of Carcinogens 24 chart, that lists ten characteristics that are 25 considered when IARC makes a determination of</p>

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<p>1 carcinogenesis.</p> <p>2 Do you see that chart?</p> <p>3 A. Yes.</p> <p>4 Q. And --</p> <p>5 MS. SHARKO: I object to the form of the</p> <p>6 question. Assumes facts not in evidence.</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. Do you use carcinogenesis synonymously with the</p> <p>9 development of cancer?</p> <p>10 A. So carcinogenesis is the progression of cancer. Details</p> <p>11 are important. I mean, it depends on what step could --</p> <p>12 it depends on what step in that process of cancer</p> <p>13 development we're talking about. So carcinogenesis</p> <p>14 could be from the precursor lesion to the early stage</p> <p>15 disease to -- Stage 1 to Stage 2, and it's the continuum</p> <p>16 of cancer development. But I think in reference to this</p> <p>17 article they're talking about the transformation, the</p> <p>18 path of transformation, the early stage. Is that --</p> <p>19 Q. More the initiation phase --</p> <p>20 A. Yes.</p> <p>21 Q. -- than the progression phase, would you agree?</p> <p>22 A. I believe so, yes.</p> <p>23 Q. And among -- well, let's look at the hand -- key</p> <p>24 characteristics. Is malignant transformation required</p> <p>25 in IARC's methodology?</p>	<p>Page 78</p> <p>1 exhibited by established human carcinogens.</p> <p>2 Dr. DiFeo, do the authors of this paper state</p> <p>3 that it's based on a workshop where an international</p> <p>4 working group of experts identify the ten key</p> <p>5 characteristics for IARC?</p> <p>6 A. So if I understand your question, similar to how the NIH</p> <p>7 assembles experts in a certain field, it seems like the</p> <p>8 IARC requested that these experts get together and come</p> <p>9 up with a criteria that they can use to define whether</p> <p>10 carcinogens have transformative -- are implicated in</p> <p>11 carcinogenesis. And this group of experts came up with</p> <p>12 a recommendation, right, of ten characteristics that</p> <p>13 they can use to define whether a carcinogen plays a role</p> <p>14 in carcinogenesis. And those ten characterizations are</p> <p>15 defined --</p> <p>16 Q. Okay.</p> <p>17 A. I'm not done. I'm sorry. Those ten characteristics are</p> <p>18 defined on Table 1. And you had asked me whether</p> <p>19 transformation is one of them, and as you can see,</p> <p>20 Number 9 is transformation. And what I find interesting</p> <p>21 is that, essentially, the others are all contributed to</p> <p>22 transformation, they're all kind of characteristics that</p> <p>23 eventually lead to transformation.</p> <p>24 Q. And that was not a question I asked, although we are</p> <p>25 going to get to that.</p>
<p>1 A. Yes.</p> <p>2 MS. SHARKO: I object to the form of the</p> <p>3 question. You keep saying is this IARC's methodology,</p> <p>4 and the paper clearly says it's a proposal. So I think</p> <p>5 this is misleading.</p> <p>6 MS. THOMPSON: I don't think that's true. I</p> <p>7 could find it, but this methodology was applied, I</p> <p>8 believe it says, from 100 on. But that's fine. Let's</p> <p>9 call it IARC's proposal and we can confirm that.</p> <p>10 MS. SHARKO: Well, no. I -- Dr. Thompson,</p> <p>11 respectfully, I object, it's not IARC's proposal, it's</p> <p>12 the Smith Group's proposal. It says that in the second</p> <p>13 column on page 714, and it says that at the bottom of</p> <p>14 the section in the third column on 714. I mean, you can</p> <p>15 ask Dr. DiFeo, obviously, whatever you --</p> <p>16 MS. THOMPSON: Okay.</p> <p>17 MS. SHARKO: -- want about this paper, but I</p> <p>18 object to you calling it as -- calling it IARC's</p> <p>19 methodology, when it specifically is not, according to</p> <p>20 the authors.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Okay. Under Objectives in the abstract it says, IARC,</p> <p>23 therefore, convened two workshops in which an</p> <p>24 international working group of experts identified ten</p> <p>25 key characteristics, one or more of which are commonly</p>	<p>Page 79</p> <p>1 But we'll refer to this as the IARC working</p> <p>2 group determination of key characteristics of</p> <p>3 carcinogens. Let's go to the table. And you will agree</p> <p>4 that cell transformation is included under the ninth</p> <p>5 criteria, correct?</p> <p>6 A. Yes.</p> <p>7 Q. You'll also agree that the IARC working group states</p> <p>8 that of these ten characteristics, one or more are</p> <p>9 considered for the determination of carcinogenesis?</p> <p>10 A. So I don't see that. Where does it say one or more?</p> <p>11 Q. In the abstract that we just read, under Objectives and</p> <p>12 Methods.</p> <p>13 A. I don't see the one or more. I'm sorry.</p> <p>14 Q. The working group of experts identified ten key</p> <p>15 characteristics, one or more of which are commonly</p> <p>16 exhibited by established human carcinogens.</p> <p>17 MS. SHARKO: If I may, Dr. DiFeo, she's</p> <p>18 referring to Objectives.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Did I read that correctly from the abstract?</p> <p>21 A. Oh, I see. I see. Sorry, I was --</p> <p>22 MS. SHARKO: I was just pointing out to her</p> <p>23 where it is.</p> <p>24 THE WITNESS: Sorry. I found it. Okay.</p> <p>25 MS. THOMPSON: I'll give you some leeway --</p>

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<p style="text-align: right;">Page 82</p> <p>1 let me just make a statement. I'll give you some leeway 2 on looking to Ms. Sharko for guidance, but this is -- 3 you need to answer the questions without any input from 4 Ms. Sharko. 5 And, Susan, if you're going to direct her to a 6 place, just let me know that's what you're doing, 7 because it's kind of hard on Zoom to, you know, 8 understand what the interaction is.</p> <p>9 MS. SHARKO: Okay. But to be clear, I have 10 given Dr. DiFeo no input or guidance on how to answer 11 questions. I was trying to assist you so that the clock 12 isn't run out while Dr. DiFeo's trying to find something 13 you're referring to. And so I simply pointed her to 14 where you were reading from. And then you may not have 15 heard me, but I said to you, I'm pointing out to 16 Dr. DiFeo where you're reading from, okay. But let's go 17 on.</p> <p>18 MS. THOMPSON: And I didn't mean to suggest 19 you were doing anything inappropriate. I just want to 20 make sure that I know what's going on.</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. So let me just ask you the question, Dr. DiFeo. This 23 working group from IARC does not require that all ten of 24 these key characteristics of carcinogenics be met to 25 make a determination of carcinogenics, do they?</p>	<p style="text-align: right;">Page 84</p> <p>1 determination that an agent is carcinogenic? 2 A. Yeah. Well, it's on the characteristics of a carcinogen 3 on Table 1. 4 Q. That wasn't my question. Is there anywhere in this 5 paper where the authors state that cell transformation 6 has to be established before IARC can make a 7 determination that a substance is carcinogenic? 8 A. I think I would have to go through the paper again and 9 read through it. If you give me the time to do that 10 again, I can maybe look at that specifically and see if 11 they state it as specifically as that. But in order for 12 something to be defined as a carcinogen, it itself has 13 to be able to induce cancer. And that means turn a 14 normal cell into a cancer cell. And that is defined as 15 transformation. 16 Q. But what we're talking about is how IARC or the working 17 group believed the criteria or the characteristics that 18 IARC should consider when determining carcinogenesis, 19 correct? 20 A. Again, I -- this was a proposal by a group of experts. 21 I don't -- I don't work for IARC, I don't know whether 22 IARC currently utilizes this proposal. I don't know if 23 this was utilized for talc. Because these are -- these 24 assays were not used in the studies I saw. And, 25 actually, I was looking in this manuscript --</p>
<p style="text-align: right;">Page 83</p> <p>1 A. So it's hard for me, again, I have not spent a lot of 2 time reading this, but I would be shocked if just one of 3 these is sufficient to induce neoplastic transformation. 4 Because, actually, if you read the bottom of the table, 5 it says, Any of the ten characteristics in this table 6 could interact with one another. So a lot of these tend 7 to be redundant. So, for instance -- so Number 10, 8 right, so if you look at that alter cell proliferation, 9 cell death and nutrient supply, that is a -- that 10 includes so many different things, such as 11 proliferation, apoptosis, growth factors. It's meant to 12 actually be a lot of different things. So it's a very 13 comprehensive list, but then a lot of them are very 14 redundant, so I don't know the criteria they used to 15 come up with those ten characteristics without going to 16 the references, right? Because this was just a proposal 17 they put together. And I'm assuming they include a lot 18 of references in this proposal that I don't have access 19 to right now, and I would like to -- and I would like to 20 look at.</p> <p>21 Q. Well, let me just ask you questions based on the article 22 itself, and if you can't answer them you can just say 23 you can't answer them.</p> <p>24 Is there anyplace in this article that states 25 that cell transformation has to be established before</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. But you don't know -- 2 A. Sorry, I'm not done. 3 I was looking in this paper whether talc was 4 one of the compounds, and it wasn't. And they tried to 5 some of these assays -- 6 Q. Did you look at -- 7 A. I'm not done. 8 MS. SHARKO: Wait. She's not done. 9 THE WITNESS: They tried to use some of these 10 assays in the manuscripts I read, and talc did not show 11 any of those ten characteristics. And, actually, that's 12 why my opinion is that talc is not a carcinogen and is 13 not transformative. And I don't know if IARC utilized 14 this -- these characteristics to define talc as being on 15 its list. So it's hard for me to assess or answer your 16 questions based on just reviewing this proposal in the 17 last ten minutes. 18 BY MS. THOMPSON: 19 Q. Are you finished? 20 A. Yes. 21 Q. Did you review the IARC working group's monograph on 22 talc not containing asbestos fibers from 2010? 23 A. As I mentioned, I didn't -- IARC was not included in 24 my -- I didn't take a deep dive into IARC's 25 recommendations and their monograph data, I did not.</p>

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<p style="text-align: right;">Page 86</p> <p>1 Q. Do you think that would have been an important document 2 for you to review?</p> <p>3 A. So I did look at -- so they reference a lot of papers in 4 that monograph, so I looked at the actual original data 5 in some of -- that was reported in that. So, like, I'd 6 rather go to the source and look at some of the 7 preliminary -- the data that was referenced in that.</p> <p>8 Q. Did you look at the IARC working group's monograph from 9 2012 that looked at asbestos and talc-containing 10 asbestos fibers that determined that asbestos and 11 talc containing asbestos fibers causes ovarian 12 cancer? Did you review that monograph?</p> <p>13 MS. SHARKO: Object to the form. 14 You can answer.</p> <p>15 THE WITNESS: If you can -- I have to -- you 16 have to pull that up. I don't recall. I read so many 17 things. If you want to pull it up or show me. I don't 18 recall. If you can show me the document, it may help.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. You don't recall whether you reviewed the IARC working 21 group's monograph on asbestos and asbestos talc from 22 2012?</p> <p>23 A. I do not recall. As I mentioned, I reviewed a lot of 24 papers and I read many papers. It's my job. So I don't 25 remember. But if you pull it up, that may help me</p>	<p style="text-align: right;">Page 88</p> <p>1 in Ovary, I've not seen it. However, given that I work 2 in cancer in general and I'm part of the Rogel Cancer 3 Center. I do have colleagues that work in other 4 cancers, such as mesothelioma. There may be some data 5 there, but I don't want to speak to that because that's 6 a cancer I don't work on, so I don't know. I don't 7 know.</p> <p>8 Q. And, again, that's a perfectly fine answer.</p> <p>9 A. I don't know.</p> <p>10 Q. I won't hold it against you if you don't know something.</p> <p>11 Number 2, is talc genotoxic?</p> <p>12 A. No.</p> <p>13 Q. Is asbestos genotoxic?</p> <p>14 A. Yes. In --</p> <p>15 Q. I'm sorry, your answer is?</p> <p>16 A. Yeah. I've seen that in some literature in, again, 17 mesothelioma, I believe, at certain doses they've shown 18 that it could be genotoxic.</p> <p>19 Q. Number 3, alters DNA repair or causes genomic 20 instability.</p> <p>21 Would that apply to talc?</p> <p>22 A. No.</p> <p>23 Q. Is there any data or published literature that has 24 looked at that issue with talc?</p> <p>25 A. I believe -- so I think certain manuscripts try to look</p>
<p style="text-align: right;">Page 87</p> <p>1 remember that specific document.</p> <p>2 Q. Well, we may pull it up. I'm just surprised that 3 wouldn't have stood out to you.</p> <p>4 But let's go through the key characteristic.</p> <p>5 And are there any of these key characteristics that you 6 would not have included on this list of 10?</p> <p>7 A. No.</p> <p>8 Q. And these key characteristics are very similar to the 9 hallmark of cancer as described by Hanahan and his 10 colleagues, wouldn't you agree?</p> <p>11 A. Yes.</p> <p>12 Q. And I want to go through some of these and ask you about 13 whether or not they would apply to talc and asbestos, 14 and I'm just not asking for your criticism of the papers 15 that have described it, but just as to has it been 16 described. We can get later to whether it's valid or 17 not, fair?</p> <p>18 Is there any literature on number 1 that talc 19 is electrophilic or can be metabolically activated that 20 you're aware of?</p> <p>21 A. I have not seen data that show that talc can form DNA or 22 protein adducts in the literature that I've read.</p> <p>23 Q. How about asbestos?</p> <p>24 A. So from the limited asbestos literature that I've looked 25 at, and again, that's been mainly focused a little bit</p>	<p style="text-align: right;">Page 89</p> <p>1 at that and did not show any evidence of it.</p> <p>2 Q. Would that be characteristic of asbestos?</p> <p>3 A. Again, I don't -- not in ovarian cancer. I have not 4 seen any evidence of that.</p> <p>5 Q. Number 4, there is evidence in the peer-reviewed 6 literature that talc can induce epigenetic alterations, 7 is there not?</p> <p>8 A. I've seen that from the literature I referenced in 9 macrophages, there's some data that talc can alter 10 epigenetic modifications in macrophages.</p> <p>11 Q. And asbestos can induce epigenetic alteration, would you 12 agree?</p> <p>13 A. Again, I have not reviewed that literature with 14 asbestos.</p> <p>15 Q. And you don't remember whether you've seen IARC 2012 or 16 not, of which we can get to. Have you looked at any 17 IARC monographs on carcinogenesis of any substance?</p> <p>18 A. Yes, I have. I just -- if you want to pull it up, I'll 19 be happy to review it with you, we can discuss it.</p> <p>20 Q. I will. I'm just asking you what you know without 21 looking at it.</p> <p>22 Do IARC monographs that you've seen provide 23 mechanistic data in the monographs, typically?</p> <p>24 A. I don't want to answer the question because I don't want 25 to say something I don't -- I guess I feel more</p>

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<p style="text-align: right;">Page 90</p> <p>1 confident if I have it in front of me like I have the 2 other manuscripts to answer that.</p> <p>3 Q. Okay. Is there evidence that talc induces oxidative 4 stress?</p> <p>5 A. I really don't -- the data's not conclusive.</p> <p>6 Q. How about pleurodesis?</p> <p>7 A. No.</p> <p>8 Q. No?</p> <p>9 A. Oh, pleurodesis?</p> <p>10 Q. Yes.</p> <p>11 A. I don't -- I'm not as familiar with that, but I 12 believe -- I don't know.</p> <p>13 Q. How about asbestos?</p> <p>14 A. I don't know.</p> <p>15 Q. Number 6, is there evidence in the peer-reviewed 16 literature that talc induces chronic inflammation?</p> <p>17 A. Can you be more specific? Are you taking now about in 18 the fallopian tube microenvironment?</p> <p>19 Q. In any environment; animal, cell, human. Is there 20 evidence in the peer-reviewed literature that talc 21 induces chronic inflammation?</p> <p>22 A. I have not seen that, no.</p> <p>23 Q. Okay. We'll get to some of that later. How about 24 asbestos, Number 6, does asbestos induce chronic 25 inflammation, or do you know?</p>	<p style="text-align: right;">Page 92</p> <p>1 not seen any evidence of asbestos-inducing 2 transformation in ovarian cancer.</p> <p>3 Q. Are you aware of any studies in which asbestos causes 4 cell transformation in culture?</p> <p>5 A. In ovarian cancer cells or fallopian tube cells, no.</p> <p>6 Q. In any cell cultures?</p> <p>7 A. I have not -- I have not explored the asbestos 8 literature for other cancers. I have -- again, I did 9 not look into that data, I have not looked into that 10 literature.</p> <p>11 Q. And if there was no evidence, would that change your 12 opinion as to whether asbestos is a carcinogen?</p> <p>13 A. No. In terms of -- because the data with mesothelioma, 14 there's mouse models that have proven the effects of 15 asbestos and cancer progression. And that's the most 16 definitive, are the mouse models and the in vivo models, 17 which actually these, I don't know if they included that 18 in this characterization.</p> <p>19 MS. SHARKO: Is this a good time for a break?</p> <p>20 We've been --</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. And based on the --</p> <p>23 MS. SHARKO: Oh, I was just going to say is, 24 this is a good time for the lunch break? We've been 25 going for over an hour again.</p>
<p style="text-align: right;">Page 91</p> <p>1 A. Again, I -- I believe in the lungs there's been evidence 2 of that.</p> <p>3 Q. Number 7, would you agree that there is some evidence in 4 the literature that talc could be immunosuppressant?</p> <p>5 A. No.</p> <p>6 Q. Asbestos, same question?</p> <p>7 A. I don't know that.</p> <p>8 Q. 8, modulates receptor mediated effects. Is there any 9 evidence in the literature that talc modulates receptor 10 mediated effects?</p> <p>11 A. No.</p> <p>12 Q. How about for asbestos?</p> <p>13 A. No.</p> <p>14 Q. Number 9, Causes Immortalization. And that's where the 15 authors include cell transformation as well. I think I 16 know your answer to this, but I'll ask it. Is there any 17 evidence in the literature that talc causes cell 18 transformation?</p> <p>19 A. No.</p> <p>20 Q. And you'll agree there are papers that address that 21 issue, but you disagree with the conclusions, am I 22 correct?</p> <p>23 A. For talc, yes.</p> <p>24 Q. And how about asbestos?</p> <p>25 A. There's -- I have not seen any -- I don't agree. I have</p>	<p style="text-align: right;">Page 93</p> <p>1 MS. THOMPSON: I think we just have number 10, 2 and then --</p> <p>3 MS. SHARKO: Oh, okay. Sure.</p> <p>4 MS. THOMPSON: -- that would be a good time 5 for a break.</p> <p>6 MS. SHARKO: Sure.</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. And based on the evidence for mouse models and other 9 animal studies, human studies with asbestos, would it be 10 plausible that asbestos could cause ovarian cancer?</p> <p>11 A. I believe there were some studies done with asbestos and 12 they did not find the development of ovarian cancer.</p> <p>13 And again, I'll go back to what I mentioned earlier, 14 when they did the studies with talc, if there was 15 asbestos in those talc products, then they would have 16 been informative and the mice would have developed 17 ovarian cancer. And there was no indication of even 18 early stages of ovarian cancer, precursor lesions, 19 mutations, so it's -- to me, my opinion is that it's not 20 plausible.</p> <p>21 Q. It's not plausible. I'm sorry, I didn't hear you.</p> <p>22 A. If there was contamination of asbestos in the talc 23 products that were used for those in vivo studies.</p> <p>24 Q. Well, my question was regarding asbestos exposure 25 itself.</p>

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<p style="text-align: right;">Page 94</p> <p>1 A. Yeah. Well, I was -- I think there were some studies 2 done with asbestos in vivo and they did not find that 3 the mice developed ovarian cancer.</p> <p>4 Q. And for that your conclusion would be that it's not 5 plausible that asbestos exposure could cause ovarian 6 cancer?</p> <p>7 A. I mean, again, I don't have all of the literature in 8 front of me. I did not do a deep dive into that area. 9 But from the limited literature I looked at, the data 10 and the results did not show it. So I don't want to 11 be -- but to date --</p> <p>12 Q. But my question --</p> <p>13 A. To date, the data I've seen, I do not think it's 14 plausible.</p> <p>15 Q. Okay. And then Number 10, and then it will be fine to 16 take a lunch break, Alters cell proliferation, cell 17 death, or nutrient supply. Is there any data in the 18 literature regarding talc and Number 10 that you're 19 aware of?</p> <p>20 A. It was attempted. And from the data I observed, it was 21 not conclusive that talc affects proliferation.</p> <p>22 Q. Asbestos, same question.</p> <p>23 A. I don't recall looking or seeing any data on asbestos 24 effect of ovarian cancer cell proliferation, so I can't 25 comment on that.</p>	<p style="text-align: right;">Page 96</p> <p>1 the effects on inflammation, but that was in reference 2 to other tissues, and not in terms of in the fallopian 3 tube or in the ovarian microenvironment.</p> <p>4 Q. Okay. So if what you're saying, that talc could induce 5 inflammation in the pleura, the peritoneal cavity and the 6 ovaries and other --</p> <p>7 A. Wait. I never said that.</p> <p>8 Q. -- locations. Let me -- I'm not finished this time. 9 But if you don't see it specifically studied 10 in the distal portion of the fallopian tubes, you would 11 not be able to say that talc induces chronic 12 inflammation.</p> <p>13 A. No, I would not say that it contributes to ovarian 14 cancer, right. That it's a transformative factor.</p> <p>15 Q. That's not my question. Does it cause chronic 16 inflammation?</p> <p>17 A. I guess I don't -- I don't feel comfortable, that's a 18 very -- I don't feel comfortable answering that question 19 because I did not examine its role in inflammation. I 20 examined -- I'm a cancer biologist, and my goal is to 21 assess the factors that cause cancer. And when I tried 22 to determine whether talc played a role in ovarian 23 cancer, I looked at all the papers that included talc 24 and ovarian cancer, and I did not find that talc had any 25 characteristics that were consistent with the</p>
<p style="text-align: right;">Page 95</p> <p>1 Q. Okay. Would you agree that at least for one or more of 2 this list of 10 there is data in the literature that 3 talc would have one of these key characteristics of 4 carcinogens described by this IARC working group?</p> <p>5 A. No, I don't agree.</p> <p>6 Q. All right. So you do not -- talc, in your opinion, does 7 not induce oxidative stress?</p> <p>8 A. No.</p> <p>9 Q. And talc, in your opinion, does not induce chronic 10 inflammation?</p> <p>11 A. Oh, sorry. I want to clarify. So I think I recall you 12 meant -- I think it -- the inflammation when I mentioned 13 may be in other cell types, potentially, but I don't 14 know the literature well in reference -- let me clarify. 15 I think maybe before when you mentioned talc's 16 effects -- and maybe I should have not referenced the 17 lung or other tissues, but at least from my literature 18 review and what I observed and what I looked at and what 19 I analyzed, I did not see that talc induced chronic 20 inflammation in the fallopian tubes in the 21 microenvironment where ovarian cancer originates. So I 22 think it's very important to speak about, when we're 23 thinking about cancer progression and initiation, the 24 details are essential. It -- so I just wanted to 25 clarify that. I now remember that I may have mentioned</p>	<p style="text-align: right;">Page 97</p> <p>1 transformation. Yes, inflammation is a component, 2 potentially, of some cancers, but I was not looking at 3 talc's role in inflammation in general. So I'm not 4 going to comment -- I cannot comment on the general role 5 of talc and inflammation. It's where I stand.</p> <p>6 Q. And this will be my last question before lunch, I think. 7 And it's your opinion that chronic 8 inflammation doesn't play a role in ovarian 9 carcinogenesis, correct?</p> <p>10 A. Yes.</p> <p>11 MS. THOMPSON: Okay. And we'll go into that 12 in more detail this afternoon, after lunch. It's still 13 morning for me, but afternoon for you all.</p> <p>14 Susan, what were you thinking as far as lunch 15 break? I don't know what your situation is there.</p> <p>16 MS. SHARKO: Maybe a half hour. Come back at 17 1:00 Eastern.</p> <p>18 MS. THOMPSON: Yeah, let's shoot for a half 19 hour, and if it takes a little bit longer than that, it 20 takes a little longer than that.</p> <p>21 MS. SHARKO: Okay.</p> <p>22 (A lunch recess was taken)</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Let's go back into your report a little bit, Dr. DiFeo. 25 Do you have that in front of you?</p>

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<p style="text-align: right;">Page 98</p> <p>1 A. Yeah.</p> <p>2 MS. THOMPSON: And, Laura, we're going to be</p> <p>3 looking at the Kossai -- K-O-S-S-A-I paper. That will</p> <p>4 be marked as exhibit next.</p> <p>5 DEPOSITION EXHIBIT 8</p> <p>6 Myriam Kossai Paper - Ovarian</p> <p>7 Cancer: A Heterogeneous Disease</p> <p>8 WAS MARKED BY THE REPORTER</p> <p>9 FOR IDENTIFICATION</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. Dr. DiFeo, you're familiar with this paper, I assume?</p> <p>12 A. Yes.</p> <p>13 Q. It's cited in your report on page 9?</p> <p>14 A. One second.</p> <p>15 Okay.</p> <p>16 Q. And Citation 4, and I really just have one question</p> <p>17 about this paper. You state the term ovarian cancer is</p> <p>18 a misnomer as it does not refer exclusively to cancer</p> <p>19 that originates from the ovaries.</p> <p>20 Do you see that line? And then you go on to</p> <p>21 say, Rather ovarian cancer is an umbrella term that</p> <p>22 refers to several different subtypes of cancer that can</p> <p>23 arise from different anatomical areas of the</p> <p>24 gynecological tract, including the ovaries, fallopian</p> <p>25 tube, and uterus.</p>	<p style="text-align: right;">Page 100</p> <p>1 A. It's hard to tell. I don't know, and it would be hard</p> <p>2 to determine that.</p> <p>3 Q. If the literature says it's 76 to 90 percent, would you</p> <p>4 have any reason to disagree with that?</p> <p>5 A. I don't know. I think that seems very high, but I</p> <p>6 wouldn't -- I wouldn't know.</p> <p>7 Q. And -- but you do agree that retrograde menstruation</p> <p>8 does occur?</p> <p>9 A. More so, like, as I mentioned, endometriosis is a</p> <p>10 disease of hyperproliferative endometrium. And what</p> <p>11 occurs is the endometrium proliferates, and what you --</p> <p>12 the cells that are proliferating can then proceed up</p> <p>13 through the endometrium through the tubes and seed</p> <p>14 externally onto the ovary and beyond and sometimes into</p> <p>15 the pelvis area and the appendix. And with that you can</p> <p>16 get retrograde menstruation. So it's more so in</p> <p>17 conjunction with endometriosis.</p> <p>18 Q. But you agree that the incidence of endometriosis is</p> <p>19 much more than the incidence of retrograde menstruation?</p> <p>20 A. No, I would not agree -- I don't -- I can't agree. No,</p> <p>21 I don't. Actually, the incidence of endometriosis is</p> <p>22 probably much higher than documented, unfortunately, and</p> <p>23 that's one thing that I work on with a colleague of mine</p> <p>24 at University of Michigan where we have a center focused</p> <p>25 on endometriosis and endometriosis pain. Because not</p>
<p style="text-align: right;">Page 99</p> <p>1 I don't see any mention in the Kossai paper of</p> <p>2 uterus, so I just am wondering what you're referring to</p> <p>3 there.</p> <p>4 A. So, for instance, with the link to endometriosis or</p> <p>5 retrograde endometriosis, there's been evidence that</p> <p>6 endometrial carcinoma and clear cell can originate from</p> <p>7 the uterus.</p> <p>8 Q. Okay. Just to clarify, you're not saying that uterine</p> <p>9 cancer --</p> <p>10 A. No.</p> <p>11 Q. -- or endometrial cancer are under the umbrella of</p> <p>12 ovarian cancer?</p> <p>13 A. No, no, no, no. So there's evidence that mucinous --</p> <p>14 sorry, that clear cell and endometriotic cancer can</p> <p>15 arise from retrograde metastasis or kind of</p> <p>16 proliferation, and then those cells seed onto the ovary.</p> <p>17 That's why endometriosis is associated with ovarian</p> <p>18 cancer.</p> <p>19 Q. Okay. I just wanted to clarify that one point so that</p> <p>20 there's no misunderstanding on that.</p> <p>21 A. Sure.</p> <p>22 Q. What is the -- were you finished?</p> <p>23 A. Yeah, no, I just said sure.</p> <p>24 Q. Okay. What is the percentage, if you know it, of women</p> <p>25 who have retrograde menstruation?</p>	<p style="text-align: right;">Page 101</p> <p>1 enough women know the signs and symptoms of</p> <p>2 endometriosis because they typically attribute that to</p> <p>3 monthly cramps; and, unfortunately, don't know it until</p> <p>4 much later in age. So the incidence is higher than we</p> <p>5 predict. It's probably 80 percent to 70 percent of</p> <p>6 women probably have endometriosis at the various stages.</p> <p>7 So endometriosis is also diagnosed at various stages</p> <p>8 from 1 to 4, depending on the retrograde and the extent</p> <p>9 of dissemination during the endometriosis and how far it</p> <p>10 disseminates outside of the endometrium.</p> <p>11 Q. And is it your opinion that endometriosis occurs in</p> <p>12 80 percent of women?</p> <p>13 A. It's not -- so if you look at the -- I did not -- I want</p> <p>14 to clarify. It's not my area of expertise. I work with</p> <p>15 a lot of colleagues that work in endometriosis. There's</p> <p>16 a range. And the issue with endometriosis is that the</p> <p>17 symptoms are very vague, not many women report it. So</p> <p>18 it can range, if you look at the literature, from 30 to</p> <p>19 80 percent, given that there's -- given the vagueness in</p> <p>20 the symptoms, given the amount of women that report the</p> <p>21 diagnosis, and given the amount of physicians that</p> <p>22 actually document the number of patient cases with</p> <p>23 endometriosis.</p> <p>24 Q. What's the percentage of surgically confirmed</p> <p>25 endometriosis either by visualization or biopsy?</p>

<p style="text-align: right;">Page 102</p> <p>1 A. I don't want to give an exact number. I don't remember 2 off the top of my head. Again, I did not do that 3 research for this report. But I do think I gave -- I 4 know the percentage of endometriosis-induced ovarian 5 cancer, so that makes about, like, the risk of 6 developing ovarian cancer due to endometriosis ranges in 7 the -- 20 to 30 percent of women. So I don't know the 8 surgical numbers, though, I don't know that. That's not 9 something I looked at recently.</p> <p>10 Q. All right. Would it surprise you that it's about 11 10 percent?</p> <p>12 A. That seems low to me.</p> <p>13 Q. And you're not a gynecologist?</p> <p>14 A. No.</p> <p>15 Q. You've never visualized endometriosis in the peritoneal 16 cavity --</p> <p>17 A. Actually, I have. So --</p> <p>18 Q. -- of a woman?</p> <p>19 A. Actually, I have. So actually, like I mentioned, I work 20 with a lot of physicians and we collect samples. So one 21 thing that we do periodically, I run a translational 22 research lab and we collect samples. So myself, the 23 trainees in my lab, I make it a part of their training 24 that they go into the OR with the gynecologic oncologist 25 or any of the surgeons that are doing the surgery so</p>	<p style="text-align: right;">Page 104</p> <p>1 A. No. In this instance -- and that's why I gave the 2 references -- here, I'm referring to somatic. I think 3 later on when I talk about germline --</p> <p>4 Q. Why is it somatic?</p> <p>5 A. Yeah. So for BRCA1 and BRCA2, patients can have either 6 somatic mutations in those genes or can have germline 7 mutations. If you're going to include germline 8 mutations, it ranges to about 10 to 15 percent of 9 ovarian cancer patients have germline mutations.</p> <p>10 Q. So when you say mutation, you're just referring to the 11 tumor that's been removed from the patient?</p> <p>12 A. Yes. So these are the mutations that are in the tumor 13 and not in the blood, exactly.</p> <p>14 Q. I just wanted clarification on that.</p> <p>15 In terms of germline mutations, you mentioned 16 earlier today that genetics is an evolving field as it 17 relates to ovarian cancer. Did I paraphrase that 18 closely?</p> <p>19 A. Sorry. You mentioned genetics is an evolving field?</p> <p>20 Q. Genetics. Genetics and genetics testing is an evolving 21 area of research, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Where --</p> <p>24 A. Sorry. I said yes.</p> <p>25 Q. And by that I mean, there are mutations that are</p>
<p style="text-align: right;">Page 103</p> <p>1 they know what they're actually working with. So I have 2 been in the OR. I'm not the surgeon myself, but I've 3 seen it. And I think that's critical to the training 4 and also understanding the disease.</p> <p>5 Q. You're also not a clinical pathologist, correct?</p> <p>6 A. No.</p> <p>7 Q. Or an anatomic pathologist, correct?</p> <p>8 A. No. So if you're referring to an MD, I'm not, but I 9 work in the department of pathology, and I have trained 10 in understanding how to read PAP slides and do IHC 11 staining, and have worked in the lab, pathology 12 laboratory.</p> <p>13 Q. Okay. Let's go to page 10 of your report. And this is 14 just another statement that I want clarification on. 15 Beginning about two-thirds down the page, Genetically, 16 HGSCs have very few mutations that are common among all 17 patients, with p53 present in 96 percent of patients, 18 and BRCA1/BRCA2 mutations seen in 20 percent of 19 patients.</p> <p>20 A. Okay.</p> <p>21 Q. With the p53 present in 96 percent of patients, you're 22 referring to somatic mutations, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And with the BRCA1 and 2, you're referring to germline 25 mutations, correct?</p>	<p style="text-align: right;">Page 105</p> <p>1 determined to be deleterious, there are VUS's that are 2 determined to be benign, determined to be pathogenic, in 3 other words, there are some changes that are reported as 4 time goes on, is that right?</p> <p>5 A. Yes, that's correct.</p> <p>6 Q. My question is, where do you go for information as to 7 whether there has been any reclassification?</p> <p>8 A. Great. So there's a website called ClinVar, also 9 through NCVI, and that website documents -- especially 10 for germline mutations, that will document whether a 11 mutation has been identified in patients that have been 12 diagnosed with cancer and have a germline mutation.</p> <p>13 And, therefore, if it's found that a specific mutation 14 that previously was known to be a VUS and now there's a 15 higher percentage of patients that then have that same 16 mutation and consistently are diagnosed with certain 17 cancer, for instance, breast or ovarian cancer, then it 18 strengthens the association of that mutation, especially 19 if it's, for instance, BRCA, a gene that's already shown 20 to cause cancer, with that disease. So it's called 21 ClinVar -- C-L-I-N-V-A-R.</p> <p>22 Q. And for a clinician, would a reliable source be the NCCN 23 guidelines?</p> <p>24 A. So NCCN guidelines, that is exactly what they use for 25 guidelines for treatment, biomarkers, so on, but that</p>

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<p style="text-align: right;">Page 106</p> <p>1 will tell them the current genes that most companies 2 screen for. And will also tell them the recommendations 3 as to whether you will send the tumor sample for genetic 4 testing. For instance, a recommendation for ovarian 5 cancer currently is that every patient diagnosed with 6 ovarian cancer should get genetic testing regardless of 7 heredity or family history. And that is because of the 8 drugs that we have available.</p> <p>9 Q. But there's no list of which mutations have increased 10 risk for breast and ovarian cancer, or do you know?</p> <p>11 A. I think I've included them in the report. And, again, 12 like I said, I haven't looked in the last, I think, four 13 weeks or five weeks. It may have changed because 14 sometimes it changes. But the more common ones are 15 BRCA1, BRCA2, ATM, RAD51, PALB1 -- here, right here -- 16 RAD51C and D, MRE11A.</p> <p>17 Q. I think you've listed those in your report on page 13?</p> <p>18 A. 13, yeah. I just wanted to -- yes. Exactly. And a lot 19 of times, actually, they will include additional ones if 20 they've been associated with breast cancer as well, or 21 most companies -- so I work a lot with Tempus or 22 Foundation Medicine or Invitae -- they will include 23 additional ones if they've been -- if they have family 24 history of other cancers or if they have end --</p> <p>25 Q. Is there any other --</p>	<p style="text-align: right;">Page 108</p> <p>1 but there, you know, there could be maybe two percent 2 mutations in one gene, or five percent. And again, this 3 gets back to the whole association actually. So if 4 there's two percent of patients that have mutation in 5 gene X, how do we understand whether that's causal? 6 That's when we do the studies in the lab. Because maybe 7 two percent has a big impact. And that's actually what 8 we do, we generate a mouse model that has that mutation, 9 or we generate cells that have that mutation, and that 10 may have a big impact. And that's actually like --</p> <p>11 Q. On page --</p> <p>12 A. Sorry. Go ahead.</p> <p>13 Q. On page 13 as well, you state your -- you discuss the 14 VUS, variants of unknown significance. And describe two 15 studies, one I believe is Hall, and the other one I 16 believe is -- I can't remember the name. But they had 17 similar results, do you agree? Do you agree with those 18 studies?</p> <p>19 A. Yeah, VUS's and the BRCA gene, I believe, is one, is 20 that --</p> <p>21 Q. Yes.</p> <p>22 A. -- what you're referring to?</p> <p>23 Q. Yes. And the percentage of an original VUS in these two 24 studies that was reclassified as pathogenic or largely 25 pathogenic in the first study over a 13-year period was</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Sorry, one other thing I want to add. Again, this is my 2 area of expertise, I'd like to -- and if they have a 3 history of endometriosis, there are defined mutations 4 that cause endometriosis-induced ovarian cancer, so they 5 may also include other genes such as KRAS, ARIDA1, or 6 other genes that are known to be associated with 7 endometriosis-induced ovarian cancer.</p> <p>8 Q. And with that we were talking about genetic mutations as 9 well?</p> <p>10 A. Yeah. They include -- so typically, those companies 11 will do both germline, so they'll test the DNA from the 12 blood as well as from the tumor. So you get a readout 13 for both, whether it's genetically inherited or somatic.</p> <p>14 Q. And other than the ones listed in your report and the 15 ones that you just described that are associated with 16 endometrioid and clear cells, any others come to mind as 17 we talk today?</p> <p>18 A. Oh, there's so many. Sorry. Again, I work on some of 19 them. I don't -- PP2A is one that is mutated. I don't 20 know if you want me to -- maybe if you could elaborate. 21 But again, as I mentioned, ovarian cancer doesn't have 22 that many -- like, do you want in high-grade serous 23 cancer or are you asking about in clear cell? Because 24 there could be -- it all depends on the percentage. So 25 as I mentioned, there's not many recurrent mutations,</p>	<p style="text-align: right;">Page 109</p> <p>1 5.6 percent, so it's relatively low, would you agree?</p> <p>2 A. Yeah. Well, relatively low, though, but in a very 3 potent tumor suppressor gene. So I mean, you have to 4 think about the impact of that.</p> <p>5 Q. Fair enough.</p> <p>6 Let's move on to the section of your report 7 that is titled Experimental Models to Assess Malignant 8 Transformation. I think it begins on page 20.</p> <p>9 A. Got it.</p> <p>10 Q. Are you there?</p> <p>11 A. Got it. Yes.</p> <p>12 Q. You're faster than me.</p> <p>13 Okay. The diagram on page 22, did you create 14 the diagram that is titled Bio Assay to Test Malignant 15 Transformation?</p> <p>16 A. Yeah. So that Figure A. Those are cells that we 17 isolated --</p> <p>18 Q. Figure 1?</p> <p>19 A. Yeah, Figure 1A?</p> <p>20 Q. Oh, I see, A. Um-hum (affirmatively).</p> <p>21 A. Yes. Those are cells that we isolated from a normal 22 fallopian tube from a patient. And as I stated there, 23 they're immortalized using overexpression of hTERT, so 24 that's telomerase. So as we age, as people age or as 25 our cells age, we lose telomerase, that's one result of</p>

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<p style="text-align: right;">Page 110</p> <p>1 aging. And when our telomeres shorten, that's actually 2 what causes cells to die. So what we do to keep these 3 cells alive or immortalized is that we overexpress this 4 telomerase hTERT, and then we also inactivate p53, which 5 is exactly that gene that I mentioned that's mutated in 6 close to 100 percent of ovarian tumors. And what that 7 does is, essentially, immortalize these fallopian tube 8 cells, as we know are the precursor cells of high-grade 9 serous ovarian cancer. And that really is the 10 quintessential way -- this is the way to assess, and 11 utilizing this model is what you would want to use to 12 determine whether any factor, any gene can transform 13 these normal non-malignant cells to cancer cells, is 14 kind of what I was trying to explain in this figure. I 15 thought that -- for me as a scientist and most 16 scientists, having a visual picture is the most helpful, 17 so I thought this would be a great way to do that. And 18 what I tried to provide here was the data that we 19 generate, and some of this is published in the Nature 20 Communication paper looking at a microRNA. I didn't 21 want to include all the details of it, that's why I just 22 put oncogene 1, oncogene 2. I could tell you what those 23 oncogenes are if you would like. But one of them is a 24 microRNA we worked on, the other one is MYC, which is a 25 very well-known oncogene. And you can start to see as</p>	<p style="text-align: right;">Page 112</p> <p>1 A. Oh, I'm sorry. 2 Oh, here. So if you look at page 21, after 3 Figure 1D, I think I reference 24. Let me see if that's 4 the Nature Communications. 5 Yeah, that's it. Perfect. Oh yeah. So I do 6 cite. So after Figure 1D, page 24, it's referenced -- 7 it's -- sorry, no. It's reference 24. 8 Q. Page 24? 9 A. Sorry. 10 Q. Oh, reference 24? 11 A. Yeah. Sorry, it's page 21. Sorry about that. Page 21. 12 Q. Okay. 13 A. And it's the sixth line down. 14 Q. Knarr? 15 A. Yes. Matthew Knarr, yep. Actually, it's in -- 16 Q. I don't believe that figure is in -- 17 A. Oh, it's -- so I didn't include that. So I took -- it's 18 not the actual figure, it's data -- it's pieces of data 19 from that figure, you know, modified. It's not the 20 exact figure. 21 Q. So I'm not sure I understand. Did you create Figure 1 22 or did that appear in that peer-reviewed literature? 23 A. So data from that peer-reviewed literature is included 24 in this Figure 1. 25 Q. But not the actual diagram?</p>
<p style="text-align: right;">Page 111</p> <p>1 you put in one oncogene, the cells become, what I say, 2 like, kind of stringy and more proliferative, they start 3 growing on top of each other. Because, normally, normal 4 cells will not grow on top of each other. They undergo 5 what we call contact inhibition. And then if you put a 6 second oncogene on top of that, you start to see these, 7 actually, look like tumors that are growing on top of 8 the cell culture. 9 Does that help explain that picture? 10 Q. Well, I appreciate that information; and it does, but my 11 question was, did you create this diagram? 12 A. So are you talking about the -- oh, so I thought you -- 13 are you talking about the diagram or the picture? 14 Q. Did you create Figure 1 in your report? 15 A. Yeah, yeah. Of course. Yes. Sorry. Yes. 16 Q. Well, I just see a citation, so I didn't know whether 17 that came from the peer-reviewed literature or whether 18 it was something that you created yourself. 19 A. Oh. I thought we did include it. Sorry. I'm sorry, I 20 thought I had a citation on that. Oh, I'm sorry. I 21 thought when I referenced Figure 1 I had a citation. 22 Yes, that's -- 23 Q. I didn't see a citation and I couldn't find it in any of 24 the articles you cited. And I was just curious where 25 this Figure 1 paper --</p>	<p style="text-align: right;">Page 113</p> <p>1 A. No. No. The diagram I made to make it clear so that 2 you could understand what I was trying to describe in 3 that paragraph. 4 Q. All right. That was my question. And in this figure 5 with the mouses, it looks like they are the -- cell 6 cultures exposed or the mouse received Sub-Q injection 7 of an estradiol. Go through the process of C again and 8 on the timing of it. 9 A. Sure. So in C, we kind of go through all the hallmarks 10 of cancer. And in C, one of the major hallmarks is 11 anchorage independent growth. So one of the -- what I'm 12 trying to describe there is, so you have these cells in 13 cell culture, which the picture is in A, right? And 14 normally the cells will grow on tissue culture plates. 15 So they grow on plastic, which is that picture at the 16 very top in that Figure C, is just those cells, they 17 adhere to plastic, normal cells. But once they're 18 forced to grow in suspension, normal cells will die. 19 But if they're transformed, if they're cancer cells and 20 they acquire enough mutations, they will undergo what we 21 call anchorage-independent growth. And they form these 22 clusters or we called spheres. They're a surrogate for 23 tumors in a dish. Because some labs doesn't have the 24 ability to do mouse studies, so they kind of do these 25 surrogate in vitro assays, we call it, they do these</p>

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<p style="text-align: right;">Page 114</p> <p>1 surrogate assays in a dish. And that's what I'm 2 describing in C. And I describe that because I will 3 soon --</p> <p>4 Q. Okay.</p> <p>5 A. I review literature that I critically review in this 6 report that tries to do some anchorage independent 7 growth or soft agar studies. And I thought it was 8 important to show how those assays are done. So I 9 wanted to show a picture of that in C. That's why that 10 had that picture. Does that make sense now? Does that 11 make sense? Is that why --</p> <p>12 Q. That's helpful. Thank you.</p> <p>13 A. Thank you.</p> <p>14 Q. And so the monitor -- I'm sorry, were you finished?</p> <p>15 A. No, no. And then now if you want to -- so C is separate 16 from B. And then D is really the quintessential assay 17 that needs to be done, whether something is 18 carcinogenic, transformative, is now you take those 19 immortalized cells, again, the same picture, those 20 normal cells that are growing on the plate, and you can 21 either -- you take your gene, overexpress your gene, 22 treat it with some type of carcinogen if that's what 23 you're testing. After that, you implant them, those 24 cells that have been treated or overexpressing their 25 gene of interest, and you implant them into what we call</p>	<p style="text-align: right;">Page 116</p> <p>1 carcinogen. And this is something we do with other 2 known carcinogens for other cancers, like DEN or DBA. 3 They do this with UV light, right, for melanoma. Mice 4 that already develop cancer, ovarian cancer, which we 5 actually have these mice in our lab, you can give them 6 various agents and see if they develop ovarian cancer. 7 Or you could do the same exact thing that we did here. 8 Q. And you had that capability in your lab, I believe, 9 right?</p> <p>10 A. Yes.</p> <p>11 Q. Did you attempt to perform that type of study using talc 12 or talc with asbestos?</p> <p>13 A. No.</p> <p>14 Q. Why not?</p> <p>15 A. Getting back to the hypothesis question you asked in the 16 very beginning, hypothesis needs a strong rationale. 17 From all the data I reviewed, there's no rationale that 18 shows talc has a mechanistic role in driving ovarian 19 cancer, therefore, there was no indication that I should 20 test those studies.</p> <p>21 Q. But you would agree you can prove it using your model if 22 you had chosen to do that?</p> <p>23 A. Oh, I definitely could do that. But we explore -- we do 24 patient-driven research and a lot of our studies are 25 based on the findings that we discover from the analysis</p>
<p style="text-align: right;">Page 115</p> <p>1 mice, I mean, either the mice can be immunodeficient or 2 they could be syngeneic mice, mice that have a complete 3 immune system. And if that compound is actually 4 tumorigenic, then those mice should form tumors. And 5 that's essentially what I did in that Nature 6 communications paper, and that's why I referenced it, 7 that reference 24.</p> <p>8 Q. And the mice are then followed for 10 days to see if 9 they actually have a palpable tumor, is that correct?</p> <p>10 A. Yes. Or longer. Depending on the days. And what we do 11 is we implant it into the peritoneum, so you implant the 12 ovarian tumor cells or fallopian tube cells into the 13 peritoneum of the mice, and you get metastasis if it's 14 transformative, or you can put it under the skin of the 15 mice. Yeah.</p> <p>16 Q. And if you were to study the potential carcinogenesis of 17 talc or asbestos or a combination, is this the model you 18 would use?</p> <p>19 A. There's -- yeah. So that's exactly what we were would 20 be looking for. There's various models. So this is one 21 model we used. The other models, and it's -- which 22 would be more applicable for a carcinogen, and actually 23 even easier than these genetic models. You can take 24 genetically engineered mouse models, so mice that 25 already develop ovarian cancer, you can expose them to a</p>	<p style="text-align: right;">Page 117</p> <p>1 of patient samples. And from those findings of the 2 patient samples we analyzed, there was no indication to 3 perform those studies. And we only have a -- so, 4 therefore, we didn't perform them.</p> <p>5 Q. To your knowledge, did Johnson & Johnson perform any 6 studies based on a model similar to the one you've 7 outlined here?</p> <p>8 A. I don't know. I couldn't -- I can't -- I don't know. I 9 don't -- I don't work at Johnson & Johnson, I can't 10 speak to what they have done.</p> <p>11 Q. Did you ask?</p> <p>12 A. Who? Did I ask who?</p> <p>13 Q. Johnson & Johnson attorneys if they had the information 14 as to what studies Johnson & Johnson had performed?</p> <p>15 A. I didn't.</p> <p>16 Q. Would it have been interesting?</p> <p>17 A. I mean, no. I guess -- you know, I just expect -- you 18 know, as a scientist, if the data is relevant, if it's 19 strong, to be published, and I'll look at it when it's 20 published. I don't trust data -- I mean, if it's not 21 out there, it's not published.</p> <p>22 Q. And is it your opinion that the mouse model that you've 23 described is applicable to talc use in a human female?</p> <p>24 A. Oh, yeah. Well, yeah, the fallopian tube's from a human 25 female. I think it's -- the best that we can do without</p>

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<p style="text-align: right;">Page 118</p> <p>1 giving talc to women directly, yes.</p> <p>2 Q. And would you agree it would be unethical to give talc</p> <p>3 to women directly?</p> <p>4 A. Unethical. I can't speak to the ethics of it. I mean,</p> <p>5 I don't want to do anything a woman -- I can't force</p> <p>6 anyone to do anything they don't want to do, but -- I</p> <p>7 think -- from what I've seen, talc is safe and doesn't</p> <p>8 play a mechanistic role in ovarian cancer, so I can't --</p> <p>9 but I'm not going to force anyone to do anything.</p> <p>10 Q. Well, you're not forcing anyone to do anything when you</p> <p>11 perform a study. I assume you would get informed</p> <p>12 consent involving humans, correct?</p> <p>13 A. Sure, yeah.</p> <p>14 Q. And you don't have to get consent from the mice, do you?</p> <p>15 A. Actually, you do. No, you do.</p> <p>16 Q. Okay. You don't have to answer that question.</p> <p>17 A. No, I will. You actually do. So we have to go through</p> <p>18 a very stringent process.</p> <p>19 Q. Agreed. All right. Would your model take into</p> <p>20 consideration the genital application of talc daily for</p> <p>21 decades?</p> <p>22 A. Most -- I mean, if not -- I mean, the higher dose,</p> <p>23 because our -- adding it to a cell line is probably even</p> <p>24 higher nonphysiological doses than taking it for a</p> <p>25 decade, because we do not have evidence that --</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. The model that you've presented here.</p> <p>2 A. So I presented -- in Figure 1, I presented various --</p> <p>3 two different models. So the mouse model would, right?</p> <p>4 Q. Do you believe that the mouse model would accurately</p> <p>5 represent the exposure of a human who applies genital</p> <p>6 talc every day for 50 years?</p> <p>7 A. It's hard to, again, I think it's -- it's difficult to</p> <p>8 assess definitively. But if we're asking about the</p> <p>9 mechanism and whether it has a direct effect on proteins</p> <p>10 or DNA or functional aspects of cells, you can assess</p> <p>11 that using these models.</p> <p>12 Q. Does your model in the mouse take into consideration the</p> <p>13 uniqueness of the human female reproductive tract?</p> <p>14 A. So when you inject the cells into the peritoneum or</p> <p>15 also, I didn't mention, you could also inject into the</p> <p>16 bursa, the ovarian bursa of the mouse, which we call an</p> <p>17 orthotopic model, then you're trying to phenocopy the</p> <p>18 gyn tract or the ovarian microenvironment. Again, you</p> <p>19 try to best mimic the microenvironment that your disease</p> <p>20 is in, the context of it.</p> <p>21 Q. So are you able to answer that question; yes, it does</p> <p>22 take it into consideration or, no, it --</p> <p>23 A. Yes, it does. It does -- we -- I think we -- to the</p> <p>24 best of our ability, the combination of these models,</p> <p>25 especially that we -- the fact that we utilize</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. But you don't --</p> <p>2 MS. SHARKO: Wait. She's not done.</p> <p>3 THE WITNESS: Sorry. Because we don't have</p> <p>4 evidence that it reaches the fimbriated end of the</p> <p>5 fallopian tube. Whereas, when you add it directly to</p> <p>6 cells, you're adding it directly to the cells, right?</p> <p>7 You know that it's getting onto the fallopian tube</p> <p>8 cells.</p> <p>9 BY MS. THOMPSON:</p> <p>10 Q. But wouldn't you agree that a cell study usually cannot</p> <p>11 reproduce the dose that an actual human is getting?</p> <p>12 A. I mean, in terms of what we -- what we could reproduce</p> <p>13 is whether it has genotoxic effects, whether it directly</p> <p>14 affects the proliferative rate of those cells, right?</p> <p>15 Whether it has effects on the microenvironment because</p> <p>16 you only have one cell type. So every model has its</p> <p>17 limitations, and that's why I always mention you have to</p> <p>18 assess things in multiple models, and that's exactly in</p> <p>19 Figure 1, I have cell culture, I have mouse models, and</p> <p>20 that's where we do things in multiple models. It's the</p> <p>21 reproducibility across numerous models. Exactly the --</p> <p>22 Q. Understood. Go back to my question. Would this model</p> <p>23 take into consideration the exposure of a woman who uses</p> <p>24 talcum powder on her perineum every day for decades?</p> <p>25 A. Which model?</p>	<p style="text-align: right;">Page 121</p> <p>1 patient-derived fallopian tube cells, we do to the best</p> <p>2 of our ability recapitulate human disease.</p> <p>3 Q. Do you know what the reported latency period is for</p> <p>4 ovarian cancer with exposure to talc or asbestos?</p> <p>5 A. No, not with reported talc, but I do -- the reported</p> <p>6 latency with ovarian cancer, though, varies, but what</p> <p>7 we're finding out now that fallopian tubes are getting</p> <p>8 removed is that a woman can have a p53 signature, which</p> <p>9 is p53 mutation, which is one of the earliest</p> <p>10 precursors, sometimes seven to ten years prior to</p> <p>11 getting a stick lesion, which is that proliferative</p> <p>12 lesion, and then could sometimes have a stick lesion</p> <p>13 seven to ten years prior to getting high-grade serous</p> <p>14 cancer. Because high-grade serous cancer is actually</p> <p>15 most commonly diagnosed in postmenopausal women. So the</p> <p>16 latency of ovarian cancer varies. I don't know in terms</p> <p>17 of talc, because I don't -- that data's not clear.</p> <p>18 Q. Most women are not diagnosed with a stick lesion,</p> <p>19 they're diagnosed with ovarian cancer, would you agree?</p> <p>20 A. Yeah. I think -- now that we're getting more</p> <p>21 opportunistic, fallopian tube and ovarian removal and</p> <p>22 high-risk BRCA1, 2, fallopian tube removal, I think</p> <p>23 they're finding more stick lesions, but it is a correct</p> <p>24 assessment to say the majority of patients, given that</p> <p>25 70 to 80 percent of ovarian cancers are diagnosed at</p>

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<p style="text-align: right;">Page 122</p> <p>1 Stage 3 and 4, the stick lesions are a mass, they 2 usually do not find the stick lesions at that point. 3 Q. All right. And do your mice, in their 10 days, 4 experience pregnancy or childbirth? 5 A. These mice aren't breeding. So they don't have any 6 males so they cannot get pregnant. 7 Q. Do these mice have intercourse? 8 A. No, they're not -- there's no males present. 9 Q. Do these mice menstruate or the equivalent? 10 A. No. 11 Q. Let's turn to page 24. And there's also a diagram -- is 12 it 2 on this page? And is this a diagram that you 13 created yourself? 14 A. Yes. 15 Q. And there's no citation to it, right? 16 A. Yeah, I don't think we published this picture yet. Oh, 17 maybe, like, commentary maybe, but -- 18 Q. So did you publish, to your -- okay. 19 A. I think we have a commentary by -- I think the NCI or 20 maybe -- I don't remember. We get a lot of commentaries 21 or editorials by the -- 22 Q. So to your knowledge, this diagram has not been peer 23 reviewed? 24 A. I don't know. I don't recall. I can't -- I don't 25 recall.</p>	<p style="text-align: right;">Page 124</p> <p>1 these cells shedding, right, from these stick lesions at 2 the fimbriated end into the uterus, fallopian tubes, 3 right? And it really thinks it's -- you don't typically 4 get shedding very easily from the fimbriated end, down 5 the tube into the uterus and find anything onto the 6 tampon. So it's actually not as common as we would 7 expect. 8 Q. But we're not talking about talc coming down, we're 9 talking about from the ovary to the uterus, we're 10 talking about the talc being applied to the perineum and 11 the particles ascending through the vagina, cervix, 12 uterus to the ovary, peritoneal cavity, isn't that the 13 progression? 14 A. I mean, but it goes down, it goes up. I mean, I -- but 15 you would see -- 16 Q. But it's a two-way process though -- 17 A. Yeah, exactly. 18 Q. It's a two-way process through an open reproductive 19 tract, correct? 20 A. Yes. And that's why I mentioned what I said. 21 Q. It could go up and then come down, correct? 22 A. Yes. 23 Q. And if talc -- assume with me, if talc gets to the 24 distal end of the tube, there would be nothing that 25 would prevent it from playing a role in a stick lesion,</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Would you agree that if talc did reach the ovaries or 2 peritoneal cavity, it would reach that distal portion of 3 the tube as well? 4 A. From the data I reviewed, because they actually did 5 those type of studies, I did not see evidence of it 6 reached the distal portion, they actually looked at 7 that. 8 Q. But you don't believe it reached the ovaries or 9 peritoneum either, right? 10 A. Yeah. I didn't see evidence of that. 11 Q. So my question was, if it gets to the ovaries and gets 12 to the peritoneal cavity, it would also get to the 13 tubes, right? 14 A. If it reaches the ovaries or the peritoneum. Not 15 necessarily. I mean, I think it depends on what you're 16 looking at. I can't answer that question, no. I don't 17 know. 18 Q. If the theory is that particles can ascend through the 19 open reproductive tract, the tube is on the way to the 20 ovaries, right? 21 A. No, but -- no, actually, I'm going to dispute that. 22 Because, actually, we've been looking for many years -- 23 as I mentioned, P5 mutations and stick lesions are one 24 of the first precursor lesions, and one thing we've been 25 looking at are tampons and to see whether we can find</p>	<p style="text-align: right;">Page 125</p> <p>1 do you agree? 2 A. No. Because talc doesn't play a role in stick -- in 3 forming sticks. 4 Q. So your point there is that it doesn't play a role 5 regardless of whether the tumor originates in the tube 6 or the ovary, am I stating that correctly? 7 A. Sorry, can you -- I'm a little confused by your 8 question. Can you repeat it? 9 Q. If talc does not play a role in the development of 10 ovarian cancer, which is your opinion, correct? 11 A. Yes. 12 Q. My question is, does it matter whether the tumor 13 originates in the tube or the ovary? 14 A. No. Regardless of where it originates from, talc -- 15 Q. I mean, that was my question. It wasn't -- 16 A. Yeah, sorry. 17 Q. It wasn't a trick question. 18 A. Okay. Got it. Sorry. I was just -- no. 19 Q. Is there any reason -- well, we'll do that a little bit 20 later. 21 Are you -- have you seen information in 22 peer-reviewed literature that hypothesizes that 23 retrograde menstruation might facilitate the transport 24 of talc and asbestos particles to the tubes, ovaries, 25 and peritoneal cavity?</p>

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<p style="text-align: right;">Page 126</p> <p>1 A. No. I don't recall that.</p> <p>2 Q. Have you seen epidemiological studies where the authors</p> <p>3 state that the association of genital talc use with</p> <p>4 ovarian cancer supports the theory that ovarian cancer</p> <p>5 arises from the tube?</p> <p>6 A. Did you say distal -- sorry, I missed the beginning of</p> <p>7 your question.</p> <p>8 Q. Have you seen statements in the epidemiological</p> <p>9 literature where the authors conclude that the</p> <p>10 association of genital talc with ovarian cancer supports</p> <p>11 the theory that most ovarian cancer arises from the</p> <p>12 fallopian tube?</p> <p>13 A. Yeah, most ovarian cancers -- well, high-grade serous</p> <p>14 ovarian cancer originates from the fallopian tube.</p> <p>15 Q. But, specifically, that an association between talc and</p> <p>16 ovarian cancer, which you don't believe there is, right?</p> <p>17 A. Yes.</p> <p>18 Q. Authors that do believe there's an association with talc</p> <p>19 and ovarian cancer also believe that that association</p> <p>20 supports the theory that ovarian cancers evolve from the</p> <p>21 fallopian tube. I'm just asking if you've seen that</p> <p>22 literature.</p> <p>23 A. Oh, yeah. So, again, I didn't include a lot -- the</p> <p>24 epidemiological studies in my report. I focused more on</p> <p>25 the mechanistic studies, but I am aware of the</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. How would you classify the research showing that most</p> <p>2 ovarian cancer originates from the tube? Would you</p> <p>3 consider it a theory, hypothesis, plausible? How would</p> <p>4 you categorize that evidence?</p> <p>5 A. It is at this point -- so, I mean, that's a great</p> <p>6 question and it's really near and dear to me, because</p> <p>7 that entire field shifted as I started my career. And</p> <p>8 it really started as an association. It started with</p> <p>9 women that have BRCA mutations. If I could tell you the</p> <p>10 stories, it's actually remarkable. And it started with</p> <p>11 the fact that women that had germline mutations in BRCA1</p> <p>12 and BRCA2 started to get their ovaries and fallopian</p> <p>13 tubes removed because of genetic predisposition to</p> <p>14 developing ovarian cancer, and we have no screening for</p> <p>15 ovarian cancer. Therefore, as they were getting their</p> <p>16 fallopian tubes and ovaries removed, we never found a</p> <p>17 precursor lesion for ovarian cancer in the ovary.</p> <p>18 However, there was a very astute pathologist, Chris</p> <p>19 Crum, from Harvard, who started to thoroughly examine</p> <p>20 the fallopian tube rather than the ovary. And when he</p> <p>21 started to do that, he actually found the precursor</p> <p>22 lesion, which were p53 signatures, and then stick</p> <p>23 lesions in fallopian tubes. And it was that discovery</p> <p>24 that he found that then shifted the entire fields in the</p> <p>25 late -- in the early 2000s. But we needed to -- that</p>
<p style="text-align: right;">Page 127</p> <p>1 association reports between talc and ovarian cancer.</p> <p>2 And in those reports, what I recall is that there are</p> <p>3 associations between talc and the incidence of ovarian</p> <p>4 cancer. From what I remember is that the incidence in</p> <p>5 that association between talc and ovarian cancer varies</p> <p>6 with subtype. It wasn't just with high-grade serous,</p> <p>7 however.</p> <p>8 Q. And what did you glean from the epidemiological</p> <p>9 evidence?</p> <p>10 A. Again, what I just simply stated. It was that I don't</p> <p>11 want to delve too deep into it because it was not what I</p> <p>12 focused my efforts on. It's also not the focus of my</p> <p>13 laboratory, given that we focus on mechanistic studies</p> <p>14 and validating association studies. However, over the</p> <p>15 years, what I've heard from conferences is that there</p> <p>16 was contradictory studies showing that there's been</p> <p>17 reports that talc has been shown to be associated with</p> <p>18 ovarian cancer to various degrees, and also with various</p> <p>19 subtypes of ovarian cancer. However, those associations</p> <p>20 vary. And some cohorts have known that it does not</p> <p>21 associate -- it is not associated with ovarian cancer.</p> <p>22 Q. And you agree that you did not do a systematic review of</p> <p>23 the epidemiological evidence, the epidemiological</p> <p>24 literature?</p> <p>25 A. That's correct, I did not do that.</p>	<p style="text-align: right;">Page 129</p> <p>1 was an association. A great example, actually, for this</p> <p>2 conversation. Simply an association. And it took about</p> <p>3 close to ten years to prove that high-grade serous is</p> <p>4 definitively -- it originates from the fallopian tube.</p> <p>5 And the studies that were done to prove it were mouse</p> <p>6 models and studies as I show in this report.</p> <p>7 What they did was use genetically engineered</p> <p>8 mice -- mouse models where they mutated the four most</p> <p>9 important genes that cause ovarian cancer in fallopian</p> <p>10 tube or in the ovary. And they showed which one of</p> <p>11 those mice actually develop high-grade serous ovarian</p> <p>12 cancer. And the mice that develop high-grade serous</p> <p>13 ovarian cancer are the mice that had mutations in the</p> <p>14 fallopian tube. To prove it even further, they actually</p> <p>15 removed the ovaries from those mice. And even without</p> <p>16 ovaries and just fallopian tubes, those mice still</p> <p>17 developed high-grade serous ovarian cancer. That is a</p> <p>18 definitive and conclusive evidence that high-grade</p> <p>19 serous ovarian cancer developed from the fallopian tubes</p> <p>20 due to those four key mutations in the fallopian tube.</p> <p>21 Sorry, this is just one -- I think that's a really great</p> <p>22 example of an association, which is found by observation</p> <p>23 on a pathology report, to a clear, definitive experiment</p> <p>24 done on a mouse.</p> <p>25 Q. And I agree, it's a very interesting story, but -- but</p>

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<p style="text-align: right;">Page 130</p> <p>1 my question has to do with, is it a theory, a 2 hypothesis, or has it been proven at this point that 3 most ovarian cancer originates from the distal end of 4 the fallopian tube?</p> <p>5 MS. SHARKO: Objection, asked and answered.</p> <p>6 THE WITNESS: Should I answer it again?</p> <p>7 MS. THOMPSON: Was it?</p> <p>8 THE WITNESS: No. I can restate. So 9 high-grade serous cancer is the most common ovarian 10 cancer. Therefore, the most common ovarian cancer 11 originates from the fallopian tube.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. And in your opinion, that's been proven?</p> <p>14 A. Yes.</p> <p>15 Q. And when Fathalla -- or however you pronounce the 16 name -- first published -- when the idea was first 17 circulated, published, at that time was it a hypothesis 18 or a theory? How would you have classified it at that 19 time?</p> <p>20 A. Oh, are you talking about -- not the Chris -- sorry, I 21 think you're -- the insistent ovulation story, is that 22 the one?</p> <p>23 Q. I'm sorry, it wasn't -- that was Crum. Sorry, wrong 24 theory.</p> <p>25 A. Yeah. Yeah. So are you talking about Crum?</p>	<p style="text-align: right;">Page 132</p> <p>1 A. Yes.</p> <p>2 Q. So if a colleague in a scientific meeting came up to you 3 and said, Dr. DiFeo, is talc inert, your answer would be 4 yes?</p> <p>5 A. So I don't -- I didn't look at all -- so it's a mineral 6 finely ground that has -- I don't, you know, go into the 7 composition of talc, so most of my research, you know, I 8 didn't look at the composition of it. So I think it's 9 such a general statement. So I like to get to the 10 specifics of what exactly you're asking me. I don't 11 think they would come up and just ask me a random 12 question like that, so I would kind of ask for more 13 detail.</p> <p>14 Q. I just want to ask, change it to talcum powder, is 15 talcum powder inert? Yes or no or can't answer?</p> <p>16 A. I don't want to answer. No, I don't want to answer.</p> <p>17 Q. Sorry, I didn't hear you. I didn't hear the answer.</p> <p>18 A. I'm not going to -- no, I'm not going to answer.</p> <p>19 Q. So if you'll turn to page 27 of your report -- well, 20 before we start that, what does inert mean to you?</p> <p>21 A. So, you know, I just -- I -- like, it has no -- like, 22 the properties of it, so I usually -- it's funny because 23 I don't -- inert gasses is more, like, I'm more familiar 24 with, the properties of inert gasses. So to be honest, 25 I don't really know how to describe it. It's -- because</p>
<p style="text-align: right;">Page 131</p> <p>1 Q. No. We're talking about the theory that ovarian cancer 2 originates in the tube.</p> <p>3 A. Yeah. That's Crum's work, yeah, when he found the stick 4 lesion or the precursor lesion in the fallopian tube?</p> <p>5 Q. Yeah. Was it a theory at that time?</p> <p>6 A. Well, it was an observation -- yeah, pretty much -- I 7 wouldn't say it was a theory. It was a fact, right?</p> <p>8 You see, precursor lesions in women that have BRCA 9 mutations. And it was -- but whether that mutation 10 alone, remember the mutations didn't have ovarian cancer 11 yet, so that's why those studies needed to be done to 12 show cause.</p> <p>13 MS. THOMPSON: We're going to move to a 14 different topic. Do we need to break or want to press 15 on?</p> <p>16 MS. SHARKO: Sure, let's take a short break.</p> <p>17 MS. THOMPSON: Okay.</p> <p>18 (A short recess was taken)</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Okay. Dr. DiFeo, is talc inert?</p> <p>21 A. Inert. Meaning, it has no effect or -- so it's a 22 mineral, yeah, I guess -- in terms of its effects --</p> <p>23 Q. Was that an answer? I --</p> <p>24 A. Yeah. So inert in reference to what? In --</p> <p>25 Q. In your definition is talc inert?</p>	<p style="text-align: right;">Page 133</p> <p>1 I actually think of it as biological effects, that's why 2 I was asking in reference to what.</p> <p>3 Q. Is it inert regarding biological effect?</p> <p>4 A. It's how its impact on the cell and its -- whether it's 5 genotoxic or has metabolic effects and so on.</p> <p>6 Q. I'm not sure I understood.</p> <p>7 A. To be honest, actually, I don't -- I'm drawing a blank 8 in the --</p> <p>9 Q. Can you answer?</p> <p>10 A. Yeah, I'm actually drawing a blank in the term. I don't 11 know, actually.</p> <p>12 Q. Okay. So on page 27, under Roman Numeral XIA, your 13 statement in this section is titled Lack of Evidence 14 Showing that Talc Increases Ovarian Cancer Incidences. 15 And in this section, you cite two animal studies, I 16 believe, Hamilton and Keskin.</p> <p>17 MS. THOMPSON: Laura, if we could pull the 18 Hamilton article.</p> <p>19 DEPOSITION EXHIBIT 9</p> <p>20 T.C. Hamilton Article -</p> <p>21 Effects of Talc on the Rat Ovary</p> <p>22 WAS MARKED BY THE REPORTER</p> <p>23 FOR IDENTIFICATION</p> <p>24 BY MS. THOMPSON:</p> <p>25 Q. And you're familiar with this article, Dr. DiFeo?</p>

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<p style="text-align: right;">Page 134</p> <p>1 A. Yes.</p> <p>2 Q. And it was cited in your report, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And this study, similar to some of the studies you've</p> <p>5 described with rodents injected talc is to the bursa of</p> <p>6 rats, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And when the rats were sacrificed, the ovaries and</p> <p>9 associated tissue were cystic in appearances; these</p> <p>10 changes were the result of bursal distention.</p> <p>11 Is that what the authors found?</p> <p>12 A. Yes.</p> <p>13 Q. And right now I'm just reading in the abstract. And</p> <p>14 they go on to state that pulverized lights and electron</p> <p>15 microscope microanalysis confirmed the presence of talc</p> <p>16 in the surface epithelium, ovarian cortex and connected</p> <p>17 tissue matrix of the bursa.</p> <p>18 Is that evidence that the talc injected into</p> <p>19 the bursa of the rats traveled or was transported to the</p> <p>20 ovary and connected tissue matrix of the bursa?</p> <p>21 A. So the mouse anatomy is somewhat unique in that -- so</p> <p>22 this bursa, it's a bursa that covers the ovary,</p> <p>23 encapsulates the fallopian tube to the mice. And the</p> <p>24 mice have multiple fallopian tubes, actually. So you</p> <p>25 can't really extrapolate how far the talc traveled in</p>	<p style="text-align: right;">Page 136</p> <p>1 changes did not seem to be time-dependent, which drew</p> <p>2 some concern.</p> <p>3 Q. Are you --</p> <p>4 A. And the other thing I recall is that -- so these type of</p> <p>5 publications, without having the comparator control,</p> <p>6 like we only saw one picture from the talc injected, and</p> <p>7 not any of the controls, to draw a comparison ourselves.</p> <p>8 I think it's difficult to determine. There's a lot of</p> <p>9 variability in mice work in general. So I think it's</p> <p>10 important to just also determine whether these changes</p> <p>11 are just due to random biology. And it's unclear how</p> <p>12 they quantified these differences, whereas, the</p> <p>13 statistics -- these are just statements, but there's no</p> <p>14 statistics validating these statements.</p> <p>15 Q. So do you have criticism of the Hamilton study performed</p> <p>16 in 1984?</p> <p>17 A. So as I just mentioned, I think these -- with just --</p> <p>18 I'm looking at these right now and just would state, as</p> <p>19 you mentioned, that -- you asked me a question, I think</p> <p>20 what we're seeing is there's no effects of the talc</p> <p>21 on -- I can't make assessment of the effects of talc on</p> <p>22 the fallopian tube or that ovary because I don't have a</p> <p>23 comparison or a picture of the comparator controls.</p> <p>24 Q. Well, let's look at what the authors have to say.</p> <p>25 On the last paragraph of the Results section,</p>
<p style="text-align: right;">Page 135</p> <p>1 the mouse. So I can't -- I won't -- I can't tell you if</p> <p>2 it traveled anywhere because they injected it directly</p> <p>3 into the bursa. So there was no traveling of the talc.</p> <p>4 Q. So if the authors concluded that this was evidence of --</p> <p>5 well, just scratch that.</p> <p>6 And there were histologic changes noted in the</p> <p>7 mouses or the rats in which talc was injected, correct?</p> <p>8 A. I think, though, there are histologic changes in both.</p> <p>9 I mean, I think any time you're going to inject any</p> <p>10 compound directly into the bursa, there's going to be a</p> <p>11 response or some effect. But I think they highlight --</p> <p>12 Q. Go to page 10 --</p> <p>13 A. They do highlight the papillary changes, though, seeing</p> <p>14 that epithelium did not have to do with any type of</p> <p>15 reaction to inflammatory response, right, so I think I</p> <p>16 noted that in my report.</p> <p>17 Q. But the papillary changes were only seen in the injected</p> <p>18 rats, correct?</p> <p>19 A. I would just like to make sure I state everything</p> <p>20 correctly. And I think what I note here, too, if I</p> <p>21 recall, I just want to restate it, there was many, many</p> <p>22 articles. I just want to remember exactly the data that</p> <p>23 was posted for this is -- I'm trying to look for the</p> <p>24 normal controls. And if and when they had those, and</p> <p>25 whether it was time dependent. And I recall that the</p>	<p style="text-align: right;">Page 137</p> <p>1 just before Discussion, states, Electron microscopy</p> <p>2 reveals a heterogeneously sized population of particles</p> <p>3 deeply embedded in the ovarian tissue, and on rare</p> <p>4 occasions, small particles were seen within individual</p> <p>5 surface germinal epithelial cells.</p> <p>6 That was with the injected rats, correct?</p> <p>7 A. Let me just -- again, these are very specific questions.</p> <p>8 I want to make sure I'm 100 percent accurate when I</p> <p>9 answer you.</p> <p>10 I mean, that's a statement they make based on</p> <p>11 Figure 3, yeah. Was that your question?</p> <p>12 Q. Let's move on to the Discussion. I'm sorry, that it</p> <p>13 you --</p> <p>14 A. No, I wasn't sure what your question was. I mean, yeah,</p> <p>15 they state that there. Okay. But again, I want to say,</p> <p>16 I'm not -- these are not common assays that I do in my</p> <p>17 laboratory. I'm a cell biologist, I'm not a chemist, I</p> <p>18 don't do electron microscopy, so I don't necessarily</p> <p>19 feel comfortable or -- I mean, I don't typically do</p> <p>20 these assays, so it's not something I would want. But</p> <p>21 what I would -- what I do do is review manuscripts,</p> <p>22 review papers. And what I can say, you cannot be</p> <p>23 critical of these type of -- of this data, because we</p> <p>24 have no controls. And when I see something like this</p> <p>25 where they just have an N of one and show you one</p>

<p style="text-align: right;">Page 138</p> <p>1 picture, what's lacking from this type of data is do the 2 controls have this similar profile, how many samples did 3 you analyze, is this commonly seen across -- usually, 4 you need at least five mice that have a similar pattern. 5 So all of this is saying there's a statement. Yes, you 6 saw this, but how common is it, where are the 7 statistics.</p> <p>8 Q. And you'd agree that there were control rats; there were 9 rats that were injected and rats that weren't injected, 10 correct?</p> <p>11 A. Yes. And that's why, why didn't you include pictures, 12 why didn't they include quantification of that.</p> <p>13 Q. Well, I'm not sure Dr. Henderson is around to ask that, 14 but --</p> <p>15 A. I'm sorry. I know.</p> <p>16 Q. What we're looking at here is whether there is a 17 reaction in animal tissue to -- when exposed to talc. 18 And at least with what these authors say, that there are 19 differences between the mice that were not injected and 20 the mice that were injected with talc, would you agree 21 with that?</p> <p>22 A. No. Because you can't make --</p> <p>23 Q. Okay. Well --</p> <p>24 A. Sorry, I'm not done. You cannot make that type of 25 statement without having a control. You can't say</p>	<p style="text-align: right;">Page 140</p> <p>1 A. No.</p> <p>2 Q. So you -- it's your opinion that the bursal distension 3 occurred in both the control and the injected rats?</p> <p>4 A. My opinion is I cannot make an assessment of this data 5 without seeing the actual data.</p> <p>6 Q. Okay. And the authors also state that the papillary, in 7 the next paragraph, it is of particular interest that 8 papillary changes were seen in the surface epithelium of 9 a proportion of the injected ovaries, for it is from 10 this epithelium that most ovarian epithelial neoplasms, 11 both benign and malignant, are thought to arise. 12 This was before the introduction of the theory 13 of tubal origin, but the authors found it interesting 14 that the papillary changes were seen in the injected 15 rats. Do you agree that that's what the authors state?</p> <p>16 A. It's written there. That's all I -- it's written there.</p> <p>17 They say it.</p> <p>18 Q. Does this -- does the Hamilton study demonstrate that 19 talc is inert when injected in the bursa of rats?</p> <p>20 A. I can't -- the Hamilton study, the data from the study 21 is inconclusive.</p> <p>22 Q. Did the Hamilton study demonstrate that talc has no 23 biological effect when animal tissue is exposed?</p> <p>24 A. I can't make any conclusive assessment of the data.</p> <p>25 What I would say has no --</p>
<p style="text-align: right;">Page 139</p> <p>1 there's a difference without knowing what the baseline 2 is. Sorry. It's just infuriates me as a scientist.</p> <p>3 Q. Well, let's look at the discussion. And I agree that 4 you -- I mean, I understand your conclusions may be 5 different than the authors, but let's see what the 6 authors say because neither one of us have additional 7 pictures.</p> <p>8 Discussion, In rats, intrabursal talc 9 injection was followed by changes in the ovaries and its 10 associated tissues.</p> <p>11 You would agree that the authors are stating 12 that there were changes in the injected rats that 13 weren't noted in the control rats, would you agree with 14 that?</p> <p>15 A. That they're stating that, they're stating that.</p> <p>16 Q. Okay. And then regarding the bursal distention later in 17 that paragraph, Unfortunately, bursal distention 18 occurred as an unforeseen complication, this probably 19 resulting from talc-induced fibrosis and obliteration of 20 the small channel which normally allows communication 21 between the cavity where the ovary lies and the 22 peritoneum.</p> <p>23 And do you agree that the bursal distention, 24 probably from the talc-induced fibrosis was -- occurred 25 in the injected rats, not the control rats?</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. Is Hamilton --</p> <p>2 A. Sorry. Go ahead.</p> <p>3 Q. Are you finished?</p> <p>4 A. Yeah, sure.</p> <p>5 Q. Does the Hamilton study demonstrate in any way that talc 6 cannot reach the ovaries in the rat if it's injected 7 into the bursa?</p> <p>8 A. In my opinion, if the results were more meaningful and 9 more conclusive, they would have included more than just 10 one picture of one ovary. And there would be statistics 11 and P values included, and there would be a dose 12 dependent effect showing that talc reached the ovary, 13 so -- and they do not show that.</p> <p>14 Q. Let's go to the other study you include in this section, 15 and that is the Keskin study.</p> <p>16 MS. THOMPSON: And we'll mark that exhibit 17 next.</p> <p>18 DEPOSITION EXHIBIT 10</p> <p>19 Nadi Keskin Study Re:</p> <p>20 Long-Term Talc Exposure</p> <p>21 WAS MARKED BY THE REPORTER</p> <p>22 FOR IDENTIFICATION</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Ready?</p> <p>25 A. Yeah.</p>

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<p style="text-align: right;">Page 142</p> <p>1 Q. And this is a study that actually exposed rats to 2 peritoneal or intravaginal talc, agreed?</p> <p>3 A. Yes.</p> <p>4 Q. And going to the Discussion section here on page 929, 5 the authors state, Talc documentation -- last paragraph 6 on that page -- are you there?</p> <p>7 A. Not yet. Hold on, please. Sorry. The last paragraph 8 of the discussion you said?</p> <p>9 Q. Well, beginning, Talc application.</p> <p>10 A. Okay.</p> <p>11 Q. Talc application has unfavorable effects on female 12 genital systems, particularly on ovaries and fallopian 13 tubes. It usually manifests itself in the form of 14 tissue injury, macrophage infiltration, and an increased 15 rate of infections and development of adhesions. 16 Do you agree that that was for the authors' 17 description of their findings?</p> <p>18 A. So I did -- so these studies were a unique study in 19 which they did a pretty invasive direct intravaginal 20 application of talc, as well as intraperitoneal 21 application of talc at various doses. And what they 22 found is, which is what you would commonly find when you 23 add a foreign substance to our -- to any -- to a body, 24 mouse, human, and the body reacts, such as if you get an 25 infection, you have an inflammatory response. And</p>	<p style="text-align: right;">Page 144</p> <p>1 A. No, they did not.</p> <p>2 Q. Okay. And further in that --</p> <p>3 A. But interestingly -- sorry.</p> <p>4 Interestingly, the group that didn't receive 5 anything they still had ovarian infections and tubal 6 occlusions.</p> <p>7 Q. Well, let's go further down in that paragraph we just 8 read. In the present study, compared to the control, a 9 significantly increased rate of infection was found 10 among the rats exposed to talc, which was particularly 11 prominent for endometrial tissue, uterine tubes and 12 pelvic perineum. These tissues exhibited epithelial 13 tissue injury, macrophage, infiltration, and adhesions. 14 And the authors are describing the differences 15 between the rats exposed to talc and the controls, 16 correct?</p> <p>17 A. Yes, they are.</p> <p>18 Q. And the conclusion on the last page, In conclusion, the 19 present study demonstrated unfavorable effects of talc 20 on female genital systems in the form of foreign body 21 reaction, infection, or increased adhesions rather than 22 neoplastic. 23 That is the author's conclusion, correct? 24 MS. SHARKO: Object to the form. 25 THE WITNESS: So that is exactly -- actually,</p>
<p style="text-align: right;">Page 143</p> <p>1 that's what they stated in that discussion.</p> <p>2 Q. And you do know that Dr. Keskin's rats were divided into 3 four groups, correct?</p> <p>4 A. Yes.</p> <p>5 Q. One group received no intervention; meaning, no 6 application of any substance, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And group two also served as a control and had saline 9 administered, correct?</p> <p>10 A. I believe -- let me just double-check. So I just want 11 to -- I read this a while ago, so I just want to be 12 100 percent sure that I'm agreeing. Just -- okay, 13 group 1 is -- yes, then 2 was a control in saline, yes. 14 Intravaginal --</p> <p>15 Q. When the authors state that -- oh, sorry, are you 16 finished?</p> <p>17 A. Oh, no. I just wanted to confirm that 2 was with the 18 intravaginal injection. Okay. Thank you. Sorry. Go 19 ahead.</p> <p>20 Q. So when the author states, Talc application has 21 unfavorable effects on female genital systems, 22 particularly the ovaries and fallopian tubes, they're -- 23 they are stating the findings of the rats that received 24 the application of talc, correct? Not the controls. 25 The controls didn't receive any talc, correct?</p>	<p style="text-align: right;">Page 145</p> <p>1 I think I stated in my report that talc did show foreign 2 body reaction. And it's because they injected foreign 3 substance directly into the IP, intraperitoneal or 4 intravaginally. And how this connects to ovarian cancer 5 is unclear, given that there was no neoplastic or 6 pre-neoplastic evidence. It's just -- and that's what 7 you just stated in your statement that they said. They 8 highlight that in their discussion as well. There's no 9 neoplastic changes.</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. I believe that was my question. What the authors 12 concluded.</p> <p>13 Does this study in any way demonstrate that 14 talc is inert?</p> <p>15 A. So I guess -- so when -- inert, so again, the 16 histological changes, again, is an observation. And in 17 this case, I would say that it doesn't -- it's very -- 18 it's a descriptive study, so I still don't feel 19 confident enough to say -- I would say it's inert. 20 There's no effect on -- biological impact on the tubes 21 or the ovary.</p> <p>22 Q. So in contrast to what the authors concluded, you would 23 state that this study did not show any biological 24 effect?</p> <p>25 A. It shows that the ovaries and the tubes are reacting to</p>

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<p style="text-align: right;">Page 146</p> <p>1 a foreign substance, right, so potentially, through 2 immunohistochemistry. There's no markers, like 3 inflammatory markers that they look at. We're just 4 looking at morphological changes. Here, again, a very 5 descriptive analysis. So it's hard to -- right, H and E 6 is just showing you the morphology of these cells. It's 7 hard for me to critically assess what is functionally 8 occurring and what is biologically occurring to these 9 tubes or ovary. So I don't -- cannot make a 10 determination. And, I guess, without pictures, so I 11 just have to rely on what they have in this table and 12 one figure. So I don't feel comfortable making that 13 assessment; and based on that, I wrote in my report that 14 there's still no -- even with the vague assessment, what 15 they don't see is neoplastic changes and pre-neoplastic 16 changes. And that's the only thing you can assess with 17 H&E. That's what pathologists do when they look at 18 samples that come out of the OR. We look at the 19 differentiation state of tissue that comes out, and that 20 tells us whether a sample is normal or tumor.</p> <p>21 Q. Would you agree with me that if a tissue reacts to a 22 foreign substance, that substance is not inert?</p> <p>23 A. So yes, but the problem is I can't tell if it -- I don't 24 know how they assessed whether it reacted or not because 25 I don't see many pictures here. The only picture they</p>	<p style="text-align: right;">Page 148</p> <p>1 studies and what people had noted in the past. And 2 pretty -- that's what I base that dose -- that on.</p> <p>3 Q. What other chart did you refer to to determine that the 4 doses in this 19 -- or 2009 study were very high?</p> <p>5 A. I don't recall off the top of my head, most of them are 6 referenced in this report, but it was -- there's a 7 number of them, right. So if you go through, there's 8 100 mgs, some that have used 125 mgs, and then you kind 9 of can go back and look at some in vitro studies. So 10 it's combination of the two. And then what we then try 11 to do is extrapolate what's been shown in epi studies 12 and what patients use. And so I can't give you a 13 definitive answer in terms of what exact publication I 14 used, but from what I've seen and what experts have also 15 stated in previous publications, and based on the weight 16 of the mouse -- the rats, sorry -- the dose seems very 17 high.</p> <p>18 Q. But you didn't order that epidemiology study, correct?</p> <p>19 A. I mentioned I perused them, right. And, actually, I did 20 that for this purpose that -- I did it for that purpose, 21 like, how can I assess dosing, how do they know timing. 22 It was more to understand mechanism and amount that 23 patients would be taking. That's actually what I, the 24 main reason I actually tried to look at epidemiology 25 papers, was how can I utilize the clinical information</p>
<p style="text-align: right;">Page 147</p> <p>1 show is that there's increased follicles, unless my -- 2 and then -- let me see the other picture again. Another 3 picture on this side? So where is there a picture that 4 the cells reacted?</p> <p>5 Q. There's a foreign body reaction.</p> <p>6 A. No. But where's a picture of that, like, where do they 7 show that?</p> <p>8 Q. Well, I don't have pictures that are not included in 9 your --</p> <p>10 A. Yeah, see, that's --</p> <p>11 Q. All right. Let's move on.</p> <p>12 So your conclusion, which I think we've gone 13 over except I have one question, In sum, these studies 14 conclude that direct injection of very, <i>italics</i> 15 underlined, high doses of talc may cause foreign body 16 reaction and/or infection, but not cancer in animals.</p> <p>17 How did you determine that the doses used were 18 very high?</p> <p>19 A. Yeah, that's always a very critical question when we do 20 scientific experiments, especially given that we don't 21 even know the exposure of talc in humans, depending on 22 the general talc that's used. And that's why we do a 23 lot of dose response curves to try to extrapolate how 24 much to use. And I just went off of the literature.</p> <p>25 And, actually, a lot of that came from epidemiological</p>	<p style="text-align: right;">Page 149</p> <p>1 from epi to assess the biological impact. That's 2 usually what I use, clinical data or clinical epi papers 3 for.</p> <p>4 Q. And you're telling me that epi studies include doses 5 of --</p> <p>6 A. I wanted to see that.</p> <p>7 Q. Sorry?</p> <p>8 A. I actually wanted to see that. I wasn't sure --</p> <p>9 Q. And you found that in epidemiology studies?</p> <p>10 A. Not all of them. It was hard to find actually, and that 11 seemed to be one of the issues. It was very subjective. 12 It was very hard to issue -- find that information.</p> <p>13 Q. Moving on, did you look at the 1995 National Toxicology 14 Program, NTP, study on rats and mice?</p> <p>15 A. (No response.)</p> <p>16 Q. It's a 1995 study.</p> <p>17 A. I don't know. If you can pull that up, maybe if I see 18 the -- or if someone has that, if you have it here. I 19 don't know if it's an exhibit.</p> <p>20 Q. I think we'll go ahead and move on a little bit. Let's 21 talk some about migration, or your opinion B, the 22 section that, Talc particles cannot travel to the 23 fallopian tubes precursor lesions or ovaries, okay?</p> <p>24 A. Yeah.</p> <p>25 Q. You'd agree that that statement, Talc particles cannot</p>

<p style="text-align: right;">Page 150</p> <p>1 travel to the fallopian tubes, precursor lesions, or 2 ovaries is a bold statement?</p> <p>3 A. Sorry. Is a what statement? I missed that.</p> <p>4 Q. A bold statement.</p> <p>5 A. It's my opinion.</p> <p>6 Q. Okay. All right. But it's a pretty definitive 7 statement, correct?</p> <p>8 A. It's based on solid research that I did and data that I 9 analyzed. I didn't see any evidence of it.</p> <p>10 Q. Okay. Well, we're going to look at some of that. In 11 the first paragraph, you make the statement, Several 12 studies have attempted to demonstrate that talc can 13 migrate through the female genital tract to the ovaries 14 and peritoneal cavity. And then, However, these studies 15 were conducted under artificial conditions that do not 16 mimic the use of peritoneal application of cosmetic talc 17 and do not conclusively show that talc can migrate to 18 the fallopian tubes or ovaries. And the citations are 19 the Egli study, the Sjosten study, the Venter study, and 20 Henderson study. And we're going to look at those. But 21 there's a difference between your statement talc 22 particles cannot travel to the fallopian tubes, 23 precursor lesions or ovaries, and the studies don't 24 conclusively show, wouldn't you agree?</p> <p>25 A. I mean, they're still the same -- the concept is the</p>	<p style="text-align: right;">Page 152</p> <p>1 that sentence we just read, correct?</p> <p>2 A. No. Henderson, I state again. Wait, sorry.</p> <p>3 Q. It says, Henderson -- I'm sorry.</p> <p>4 A. Oh, no. Oh, sorry. For humans. Oh, yeah, you're 5 right. Sorry, sorry, sorry. Yes.</p> <p>6 Q. And describe for me what those artificial conditions are 7 in the human study.</p> <p>8 A. Well, you know, I feel if we're going to talk about 9 those studies, we should pull them up. Because, again, 10 I read many papers and I didn't spend time on them 11 because I wanted to focus on more the mechanistic data 12 and looking at the biological impact of talc, but I -- 13 if we want to focus in on that, let's -- I think it's 14 best, I feel more comfortable and in order to give a -- 15 the best answer, I want to pull those up. Because I 16 read them a while ago.</p> <p>17 Q. Okay. We can pull those up. But do you agree that 18 there was no discussion in your report of the human 19 study regarding migration, correct, other than that one 20 sentence we just read?</p> <p>21 A. Yes. And I think I explained why. I was more focused 22 on assessing the impact and role of talc in 23 transformation and the mechanism by which it could or if 24 it did play a role in the development of ovarian cancer.</p> <p>25 And then I wanted to hone in on what models --</p>
<p style="text-align: right;">Page 151</p> <p>1 same.</p> <p>2 Q. To you the concept of can't get there and the evidence 3 is it conclusive are the same? Which one do you go 4 with?</p> <p>5 A. So I think the title is just saying cannot travel -- so 6 I guess I'm trying -- usually, my titles are a statement 7 and I -- what I -- it summarizes what I'm about to 8 explain, and I conclusively state that, from what I'm 9 about to summarize below, is that I have reviewed this 10 literature and what I've seen is that talc particles 11 cannot travel to these locations. Therefore, in order 12 to not --</p> <p>13 Q. Okay. Well, let's --</p> <p>14 A. Sorry. I'm sorry.</p> <p>15 Therefore, in order to not repeat myself, I 16 modified that a bit and I kind of just say that it 17 conclusively does not show X, Y, and Z. Does that 18 clarify it a bit?</p> <p>19 Q. Sure.</p> <p>20 And when you say -- and you agree that this 21 entire section on migration or talc particles traveling 22 is about a page long, right?</p> <p>23 A. In my report it's -- yeah.</p> <p>24 Q. And regarding the human studies, whenever it says 73 to 25 75, there's no discussion of those studies other than in</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. Did you ever --</p> <p>2 A. Sorry. And then I wanted to hone in on what models they 3 tried to use to mimic that in mice or primates.</p> <p>4 Q. And I apologize again for appearing to interrupt, but, 5 you know, I appreciate a pause and then I say something, 6 and so it's not intentional. It's a little bit harder 7 in Zoom. I'm doing my very best. I do want you to be 8 able to finish your answers.</p> <p>9 Okay. Well, let's look at -- we are going to 10 look at those human studies, so let's go ahead and look 11 at one that I wanted to spend more time with, I think, 12 and that's the Wehner study.</p> <p>13 MS. THOMPSON: Laura, if we could pull -- I 14 believe there are two Wehner studies, the one that I 15 want now is the title On Talc Translocation From the 16 Vagina to the Oviducts and Beyond. And it's 17 W-E-H-N-E-R.</p> <p>18 DEPOSITION EXHIBIT 11</p> <p>19 A.P. Wehner Study - On Talc 20 Translocation From the Vagina 21 to the Oviducts and Beyond</p> <p>22 WAS MARKED BY THE REPORTER</p> <p>23 FOR IDENTIFICATION</p> <p>24 BY MS. THOMPSON:</p> <p>25 Q. Are you aware that Dr. Wehner was a consultant for</p>

<p style="text-align: right;">Page 154</p> <p>1 Johnson & Johnson at the time this study was performed?</p> <p>2 A. I was not aware of that. No, I was not aware of that.</p> <p>3 I'm not sure if you heard me, sorry.</p> <p>4 Q. If you look at this disclosure it says, This work was</p> <p>5 performed by Patel, Pacific Northwest Laboratories for</p> <p>6 that Cosmetic Toiletry and Fragrance Association. Do</p> <p>7 you even know what that Cosmetic Toiletry and Fragrance</p> <p>8 Association is?</p> <p>9 A. No, I don't. I think I've heard of it through</p> <p>10 discussion, but I'm not intimately familiar with it.</p> <p>11 Don't know too much about it.</p> <p>12 Q. Okay. And this was a monkey study, correct?</p> <p>13 A. Yes. Let me --</p> <p>14 Q. And going to the conclusion of the research group --</p> <p>15 first of all, is Dr. Wehner a gynecologist?</p> <p>16 A. You know, I don't know. I can't -- I don't know</p> <p>17 Dr. Wehner. I'm --</p> <p>18 Q. A monkey gynecologist?</p> <p>19 A. Again, I don't know Dr. Wehner's --</p> <p>20 Q. Okay. All right. Let's go to Dr. Wehner's conclusion</p> <p>21 based on this study done for Johnson & Johnson.</p> <p>22 The last paragraph on the next-to-the-last</p> <p>23 page. None of these studies conclusively answers the</p> <p>24 question of whether or not talc, deposited in the vagina</p> <p>25 of the human female, translocates to the oviducts and</p>	<p style="text-align: right;">Page 156</p> <p>1 spermatozoa and are unable to respond to chemotactic or</p> <p>2 physiological stimuli.</p> <p>3 Do you agree with that statement?</p> <p>4 A. So I didn't determine those characteristics of talc.</p> <p>5 And in the studies, this is -- you know, I didn't</p> <p>6 explore that, so I can't really speak to that in</p> <p>7 particular.</p> <p>8 Q. And I actually agree with that statement.</p> <p>9 They go on to say, It is, therefore,</p> <p>10 reasonable to assume that the behavior of such particles</p> <p>11 is largely governed by the laws of physics.</p> <p>12 Do you have any idea what Dr. Wehner's</p> <p>13 referring to with the laws of physics?</p> <p>14 A. I think the likelihood that it would travel up and reach</p> <p>15 the fallopian tube.</p> <p>16 Q. And how does physics apply to that?</p> <p>17 A. That you would have to have an extreme force in order</p> <p>18 for it to go all the way up the tubes and reach the</p> <p>19 fimbriated end of the fallopian tube.</p> <p>20 Q. And it's your opinion that that would take extreme</p> <p>21 force?</p> <p>22 A. Yes. Or else you'd have more sexually transmitted</p> <p>23 diseases on the tubes.</p> <p>24 Q. What is the uterine peristaltic pump?</p> <p>25 A. So that's, again, that's not my area of expertise.</p>
<p style="text-align: right;">Page 155</p> <p>1 beyond without purposeful manipulation. Our study,</p> <p>2 using state-of-the-art techniques in the most suitable</p> <p>3 animal model available, failed to provide any evidence</p> <p>4 for translocation of measurable quantities,</p> <p>5 approximately .5 micrograms, depending on the</p> <p>6 radionuclide detector system and counting time of talc.</p> <p>7 So there is one better model, correct, and</p> <p>8 that would be the human animal, wouldn't you agree?</p> <p>9 A. In humans? Yes. I mean, but would you never administer</p> <p>10 the way that it was received here. It's pretty invasive</p> <p>11 way to administer --</p> <p>12 Q. Well, there are human studies that do something similar,</p> <p>13 correct?</p> <p>14 A. Can you elaborate exactly which ones you're referring</p> <p>15 to?</p> <p>16 Q. We'll get to the human studies that you refer to in the</p> <p>17 one sentence above.</p> <p>18 A. Yes.</p> <p>19 Q. The authors go on to state, It would indeed be difficult</p> <p>20 to explain such a translocation of "insoluble inanimate</p> <p>21 particles."</p> <p>22 Is talc insoluble?</p> <p>23 A. Insolubility -- no, I think it could be some -- no.</p> <p>24 Yeah, yeah.</p> <p>25 Q. Dr. Wehner goes on to say, They lack the locomotion of</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. Would you defer to an gynecologist or a GYN oncologist</p> <p>2 for issues of that sort?</p> <p>3 A. For issues of -- sorry? What was the second part of</p> <p>4 that?</p> <p>5 Q. Regarding what -- the uterine peristaltic pump answer --</p> <p>6 A. Yeah.</p> <p>7 Q. -- for how particles could be transported?</p> <p>8 A. Most likely. That would be an area that I would consult</p> <p>9 with an expert in compression or shear stress or --</p> <p>10 actually, so or maybe biomedical engineers that are</p> <p>11 looking at the transport or someone also that looks at</p> <p>12 endometriosis or gynecologists, potentially. I mean,</p> <p>13 there's various people. That's -- that could</p> <p>14 potentially be someone --</p> <p>15 Q. Sorry. Is it your opinion that biomedical engineers</p> <p>16 have published on the uterine peristaltic pump?</p> <p>17 A. I -- again, that's not -- I have not explored that</p> <p>18 research, I don't know -- I have not looked into that.</p> <p>19 I don't know.</p> <p>20 Q. So you don't know whether that's a mechanism that would</p> <p>21 facilitate the transport of particles from the vagina to</p> <p>22 the tubes, ovaries, and peritoneal cavity?</p> <p>23 A. No, I don't -- I don't know. I don't recall looking</p> <p>24 into that in particular.</p> <p>25 Q. And then the final statement in the Wehner paper is,</p>

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<p style="text-align: right;">Page 158</p> <p>1 These laws would not permit particles to migrate 2 upstream against the direction of the beat of the 3 oviduct's ciliary epithelium, even if the particles had 4 managed to somehow breach the cervical barrier and 5 diffuse across the uterine cavity.</p> <p>6 Let's break that down a little bit. What do 7 the authors mean by upstream?</p> <p>8 A. I mean, I guess retrograde up through -- up the uterus, 9 up the fallopian tube, back up to the ovaries, right, is 10 that what you're asking me?</p> <p>11 BY MS. THOMPSON:</p> <p>12 Q. Yeah.</p> <p>13 A. Yeah.</p> <p>14 Q. Is there a -- is there a stream in the female human 15 reproductive tract?</p> <p>16 A. I think that's a terminology they were trying to use 17 just -- rather than going down with gravity, which is -- 18 it's more like, as we were talking about before, 19 retrograde menstruation going backwards, because 20 typically menstruation, everything comes down and out 21 the vagina.</p> <p>22 Q. And this study doesn't conclude there was no talc that 23 reached the internal pelvic organs, correct?</p> <p>24 A. If I recall -- wait. Let me -- I thought they didn't 25 find -- again, I have to refresh my memory because it</p>	<p style="text-align: right;">Page 160</p> <p>1 monkeys and it wasn't stated in this document.</p> <p>2 Q. Okay. Let's move to the human studies. And you cite 3 three and we're going to look at those three.</p> <p>4 Would you agree with me that there are many 5 more human studies that address whether particulates or 6 substances can migrate or be transported from the 7 external genitalia to the internal pelvic organs?</p> <p>8 A. Sorry, that those particles that could migrate?</p> <p>9 Q. Let me simplify that question a little bit.</p> <p>10 Are you aware that there are numerous studies 11 that describe migration or transport of substances 12 through that human reproductive tract?</p> <p>13 A. Again, this was not an area that I did a deep dive 14 looking at all particles that could potentially go up 15 the gyn tract, so I can't answer your question whether 16 there's numerous studies looking at what particles can 17 go up the gynecological tract. And I'm -- so I would 18 not be able to answer that.</p> <p>19 Q. Did you use migration of particles as a source term?</p> <p>20 A. No, I used migration -- talc, ovarian cancer, and if 21 migration of those -- of talc to the ovary was included 22 it would have come up in my -- in the search.</p> <p>23 Q. Okay. Let's look at the first paper you cited.</p> <p>24 MS. THOMPSON: Laura, that would be the 25 Egli -- E-G-L-I.</p>
<p style="text-align: right;">Page 159</p> <p>1 was a while back.</p> <p>2 Q. It states that there were -- there wasn't evidence of 3 measurable quantities, approximately .5 micrograms. How 4 many talc particles would be in .5 micrograms?</p> <p>5 A. I couldn't answer exactly how many particles would be in 6 that amount off -- I'd have to do the calculations 7 depending how much was injected.</p> <p>8 Q. Did the monkeys have intercourse in this study?</p> <p>9 A. I'm not sure if they stated that, so I didn't perform 10 the study. I don't know.</p> <p>11 Q. Do you think the -- Wehner would let the monkeys have 12 intercourse while he was studying them for the -- how 13 long were the monkeys studied? Well, let's move on.</p> <p>14 Do monkeys use tampons?</p> <p>15 A. I'm not sure. I don't know. I don't work with monkeys, 16 I mainly work with mice.</p> <p>17 Q. Do the monkeys have retrograde menstruation or do the 18 monkeys have menstrual periods while in the study, to 19 your knowledge?</p> <p>20 A. I think monkeys do have menstruation, actually. I don't 21 know. I don't work with monkeys.</p> <p>22 Q. I think my question was, is there any mention in the 23 study that the monkeys have intercourse, used tampons or 24 menstruated?</p> <p>25 A. I cannot answer those questions. I don't work with</p>	<p style="text-align: right;">Page 161</p> <p>1 DEPOSITION EXHIBIT 12 2 G.E. Egli Paper - The 3 Transport of Carbon Particles 4 In the Human Female Reproductive Tract 5 WAS MARKED BY THE REPORTER 6 FOR IDENTIFICATION</p> <p>7 BY MS. THOMPSON:</p> <p>8 Q. Exhibit 12. And you've read this paper, correct, it was 9 cited in your -- well, it was cited in the references.</p> <p>10 It was not discussed in your report, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And this is an early study, in 1961, correct?</p> <p>13 A. Yes. Um-hum (affirmatively).</p> <p>14 Q. And you will agree that research methods have evolved 15 since 1961?</p> <p>16 A. Yes.</p> <p>17 Q. I wasn't even -- never mind.</p> <p>18 Under the Summary and Conclusions, this paper 19 studied carbon particles, correct?</p> <p>20 A. Let me just research my memory, if that's okay. Again, 21 I read so many papers, and I do recall this paper. And 22 I thought it was important just to include because he 23 tried -- again, as you mentioned, it was an older paper, 24 there was a lot of -- there was a lack of definitive 25 data, somewhat descriptive, and you'll see why there was</p>

<p style="text-align: right;">Page 162</p> <p>1 not a lot of discussion about it, again, being 2 descriptive, being old, it was hard for me to critically 3 assess the data. So if I could just quickly scan it to 4 reacquaint myself with everything a second. Sorry. 5 Okay, I remember now. I mean, yes -- I 6 mean -- thank you very much. I appreciate it.</p> <p>7 Q. Just the last sentence under Summary and Conclusions, 8 These data, together with other work in animals and 9 humans, support the belief that the motility of 10 spermatozoa is not the chief factor in sperm transport. 11 Contractions of the muscle of the uterus or other 12 reproductive organs may be very important, and it is 13 possible that oxytocin may play a part in this process.</p> <p>14 Where was the uterine peristaltic pump 15 discovered?</p> <p>16 A. Again, I mentioned before, that's not something I'm 17 familiar with. I don't know how it relates to the 18 question you just asked me. I don't know how they can 19 make that statement based on the data they presented in 20 this paper. And I think, reading this paper again, I 21 stand by my comment that I made in the report that this 22 does not show evidence that talc in humans can reach the 23 fallopian tube or the ovary.</p> <p>24 Q. Does this study support your opinion that talc particles 25 cannot travel to the fallopian tube and ovaries?</p>	<p style="text-align: right;">Page 164</p> <p>1 Q. The first sentence in the -- we're not going to ask 2 about monkey intercourse on this one. 3 In the first sentence the authors state, In 4 this report we describe a radionuclide procedure 5 designed to evaluate the migration of a particulate 6 radioactive tracer from the vagina to the peritoneal 7 cavity and ovaries, as well as the determination of the 8 patency of the pathways between these two extremes of 9 the female reproductive system.</p> <p>10 Is it your understanding that these 11 researchers were addressing whether particulates could 12 ascend through the reproductive tract to the, in this 13 case, ovaries and peritoneal cavity?</p> <p>14 A. That's what they were -- I believe they were attempting 15 to do.</p> <p>16 Q. And what do you say they were attempting to do? They 17 actually did the study, right?</p> <p>18 A. Yeah, yeah. Yeah. I mean, when you set up a study, you 19 have a hypothesis, you set out an experimental design; 20 and until you get the results, you don't know whether 21 the results are going to fulfill the -- what you attempt 22 to put your -- attempt to do. Yes. They --</p> <p>23 Q. After the study's done, you're not attempting to do it 24 anymore, you actually, in this case, show it or you 25 don't show it and you report the findings, correct?</p>
<p style="text-align: right;">Page 163</p> <p>1 A. Yes, it supports my opinion. Or -- yes. Yes. 2 Q. And do you know how the size of the talc particle 3 compares with the size of the head of the sperm? 4 A. No, I do not. I don't -- no. 5 Q. Are you aware there are studies that show that dead 6 sperm or parts of sperm can reach the tubes and ovaries? 7 A. No. Again, that's not an area. I work in -- I'm cancer 8 biologist. I focus on what transforms normal cells to 9 cancer cells and I have not looked at dead sperm. 10 Q. And you have not looked at that data, correct? 11 A. Sorry, the dead sperm data, no. 12 Q. Okay. Let's move on to the next human study that you 13 cited. 14 MS. THOMPSON: And that is Venter, Laura. 15 DEPOSITION EXHIBIT 13 16 P.F. Venter Study - Migration 17 of Particulate Radioactive Tracer 18 WAS MARKED BY THE REPORTER 19 FOR IDENTIFICATION 20 BY MS. THOMPSON: 21 Q. And this is another study that you cited in your report. 22 Are you familiar with it? 23 A. Yeah, it's ringing a bell once I see it again, I 24 remember these older -- because it was the year I was 25 born actually. Sorry.</p>	<p style="text-align: right;">Page 165</p> <p>1 A. I'm just -- yeah, sorry, I shouldn't use the word 2 attempt. Yes, they did that. 3 Q. Okay. And I think you used that word attempt in all of 4 the human studies, and would you agree that that's not 5 promote after the a study's already been completed? 6 A. I guess these type of studies current now would not -- I 7 cannot -- I wouldn't see these type of studies being 8 performed. I haven't seen -- I'm curious why these type 9 of studies aren't performed in more recent days -- 10 years, right? Would these be approved by the IRB today? 11 Q. The Venter study was from 1979, correct? 12 A. 45 years, yes. 13 Q. Okay. The first sentence, In the female, the peritoneal 14 cavity is linked with the outside via the fallopian 15 tubes, the uterus, and the vagina. 16 Do you agree with that statement? 17 A. Sorry, where are you reading from? I missed it. 18 Q. I'm reading the first line of the actual paper. 19 A. Oh, we describe -- yeah. 20 Q. In the female -- 21 A. Oh, yes, okay. Sorry, yes. Okay. 22 Q. And I'm breaking it up into two questions. In the 23 female, the peritoneal cavity is linked with the outside 24 via the fallopian tubes, the uterus and the vagina. 25 Do you agree with that statement by the</p>

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<p>1 authors of this paper?</p> <p>2 A. Yes.</p> <p>3 Q. Did you say yes?</p> <p>4 A. Yes. Sorry.</p> <p>5 Q. And the second part of that sentence, And there is 6 evidence of migration of different substances in either 7 direction.</p> <p>8 Do you agree with that statement by the 9 authors?</p> <p>10 A. No. They don't have a reference for that. I don't 11 agree with that. Where do they -- no.</p> <p>12 Q. And then let's go to the discussion. And these are the 13 authors' conclusions, beginning with the first sentence 14 in the Discussion, Evidence is available for migration 15 of different substances in either direction within the 16 female reproductive system between the peritoneal cavity 17 and ovaries via the tubes, uterus, and vagina, and the 18 outside.</p> <p>19 Is it your opinion that evidence is available 20 for --</p> <p>21 A. No. And they also don't have a reference for that 22 statement.</p> <p>23 Q. Well --</p> <p>24 A. And they don't provide evidence --</p> <p>25 Q. And I'm trying to be careful not to interrupt you, so</p>	<p>Page 166</p> <p>1 peritoneal cavity and ovary via the tubes, uterus, 2 vagina and outside? Do you have expertise to disagree 3 with that statement?</p> <p>4 A. So what I can say is that I have the expertise to 5 critically analyze data that pertains to ovarian cancer 6 pathogenesis and gynecological cancer. And any studies 7 that assessed whether a substance or a gene or any 8 factor contributes to ovarian cancer, I have the 9 expertise to critically analyze those studies, 10 therefore, I do have the expertise to assess whether a 11 substance could potentially track or -- in either 12 direction of their reproductive tract, if those studies 13 were done in reference to whether they affected or 14 contributed to ovarian cancer.</p> <p>15 Q. Does this study support your opinion that talc particles 16 cannot travel to the fallopian tubes and ovaries?</p> <p>17 A. So I don't even know if this study provides enough 18 evidence to answer that question, but -- and that's, 19 again, why I couldn't -- I left it to one sentence in my 20 report. There wasn't enough evidence in this paper, it 21 was very descriptive, and descriptive science is hard to 22 critically analyze. It was suggestive, it was 23 descriptive. There was a suggestion that potentially it 24 could. But there was no conclusive evidence that it 25 does. And I think that's what I stated in my report.</p>
<p>1 try to be careful not to interrupt me here.</p> <p>2 A. Oh, sorry.</p> <p>3 Q. If you disagree with these authors that did this study, 4 what is your basis for the disagreement?</p> <p>5 A. I -- we have not seen evidence, at least from the data 6 that I have reviewed to date, that many particles can 7 reach -- that are injected from the vagina, can reach 8 the ovaries or the fallopian tube.</p> <p>9 Q. You don't think you've seen any data to that effect?</p> <p>10 A. No.</p> <p>11 Q. Do you have any data that states that -- I'm going to 12 use Dr. Venter's words -- different substances cannot 13 migrate in either direction in the human reproductive 14 system?</p> <p>15 A. I mean, I guess -- so there are diagnostic substances 16 that can potentially be used, and again, that's out of 17 my expertise. But when I reviewed the data pertaining 18 to talc, which was what I reviewed for this case, I did 19 not see data that conclusively showed that talc can 20 reach the ovaries or fallopian tube when injected.</p> <p>21 Q. Well, now you're saying conclusively showed. Do you 22 have the expertise to disagree with the authors who did 23 this study and stated evidence is available for 24 migration of different substances in either direction 25 within the female reproductive system between the</p>	<p>Page 167</p> <p>1 And I stand by that opinion that there's no conclusive 2 evidence that talc can travel to the ovaries or 3 fallopian tubes. And again, reading this paper again, 4 I've come to that conclusion.</p> <p>5 Q. Does something have to be conclusive to be plausible?</p> <p>6 A. Well, you needs to have solid conclusive data to -- I 7 would -- it's semantics. It all depends on the 8 impact -- sorry, I'm going to go back, I didn't finish 9 your -- but I guess my mission in life is to have an 10 impact on patients that have ovarian cancer. So 11 plausibility all depends on the impact. If there is 12 anything that would be plausible, and we're all about 13 trying to find the impact, so I think many -- it 14 doesn't -- what I'm looking for are things that are 15 conclusive. And to answer your question, I guess your 16 question was -- can you repeat the question again? 17 Sorry.</p> <p>18 Q. Well, I think my last question was, does something have 19 to be conclusive to be plausible?</p> <p>20 A. It doesn't have to be conclusive to be plausible, but to 21 strengthen the palace plausibility of it, you want to 22 conclusively confirm that it has a biological effect.</p> <p>23 Q. Let's go through the rest of Dr. Vinter's discussion, 24 beginning, Gasses, fluids -- are you with me? All 25 right. Gasses, fluids, dyes, and contrast media can</p>

<p style="text-align: right;">Page 170</p> <p>1 easily be introduced from the vagina into the peritoneal 2 cavity. And transit can take place so easily, it is 3 probably the same for many chemical substances used for 4 hygienic, cosmetic, or medicinal purposes, many of which 5 may have potential carcinogenic or irritating 6 properties.</p> <p>7 Would you agree that the authors of this study 8 thought that their findings were relevant?</p> <p>9 A. I mean, I think it's -- it's relevant in -- it's all 10 dependent on the question they're asking, and I think 11 it's important to do these type of studies, especially 12 for diagnostic purposes, right, to, for instance, as 13 they mention here, contrast agents, which are commonly 14 used, but how you can extrapolate and compare a chemical 15 agent to a gas or fluid or contrast agent is very hard 16 for me to compare the two.</p> <p>17 Q. And the next sentence, To prove this would be a great 18 practical value because migration of certain chemical 19 substances could play an important etiological role in 20 gynecological diseases and especially in carcinoma of 21 the ovaries.</p> <p>22 Same question, do you agree that the authors 23 thought the study was relevant to whether talc and 24 asbestos are the particles at issue here? You would 25 agree with that, right?</p>	<p style="text-align: right;">Page 172</p> <p>1 removed human ovaries have shown asbestos particles 2 resting on them, and there is evidence that these 3 particles originated from talc used to dust condoms. 4 So you would agree with me that talc and 5 asbestos are mentioned, the only substances mentioned in 6 this report, as a reason to study whether particles can 7 migrate to the tubes and ovaries, do you agree?</p> <p>8 A. No, I can't agree. I don't know these authors, I don't 9 know the rationale for why they would publish this 10 paper. They mention it here, but there could be other 11 reasons.</p> <p>12 MS. THOMPSON: Okay. Let's go to the other 13 human study that you cited in your report. And this one 14 is from 2004. It's the Sjosten study -- S-J-O-S-T-E-N.</p> <p>15 MS. SHARKO: Before we move on to the next 16 study, could we take a break? We've been going for a 17 little over an hour.</p> <p>18 MS. THOMPSON: Sure.</p> <p>19 MS. SHARKO: Okay. Thanks. 20 (A short recess was taken)</p> <p>21 DEPOSITION EXHIBIT 14</p> <p>22 A.C.E. Sjosten Paper - Retrograde 23 Migration of Glove Powder in the 24 Human Female Genital Tract 25 WAS MARKED BY THE REPORTER</p>
<p style="text-align: right;">Page 171</p> <p>1 A. No. I think what they're -- what they're highlighting 2 here, that this sets a foundation and the framework of 3 the type of studies that can be done and should be done. 4 So it's a descriptive study.</p> <p>5 Q. Oh.</p> <p>6 A. And what I find interesting -- oh, sorry.</p> <p>7 MS. SHARKO: No, finish your answer.</p> <p>8 THE WITNESS: What I find interesting, this 9 was done 45 years ago. So now, from 45 years ago, why 10 haven't there been similar studies done to recapitulate 11 this, because they obviously set the foundation.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. There have. We're going to look at --</p> <p>14 A. I've gotten inconclusive data that --</p> <p>15 Q. Sorry, I interrupted you. We're going to look at a lot 16 more recent, but you did not look at all the studies.</p> <p>17 There have been more recent studies. I'm using the one 18 that you cited in your report, fair?</p> <p>19 If you go to the first page, let's look at the 20 next-to-the-last paragraph of the introduction. It 21 starts this whole -- also called for inert chemical 22 testing. And I want to read that sentence.</p> <p>23 It has already been suggested that talcum 24 powder is one of these potentially dangerous inert 25 chemical products. Electron micrographic slides of</p>	<p style="text-align: right;">Page 173</p> <p>1 FOR IDENTIFICATION</p> <p>2 BY MS. THOMPSON:</p> <p>3 Q. And, Dr. DiFeo, you cited this report -- this paper in 4 your report as well, do you recall?</p> <p>5 A. Yes. I got it.</p> <p>6 Q. And this paper is 2004. And it looks at the potential 7 of cornstarch used on powdered gloves to reach the 8 peritoneal cavity, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And just looking at the abstract, the conclusion of the 11 authors was, This study has pointed out a retrograde 12 migration of starch, also in human, after a 13 gynecological exam with powdered gloves. Consequently, 14 power or any other potentially harmful substance that 15 can migrate from the vagina should be avoided.</p> <p>16 And do you agree that is the authors' 17 conclusion?</p> <p>18 A. I think the statement -- I think the powder -- sorry, 19 they make a very broad statement. So I think what 20 they've shown here in one study utilizing a small 21 dataset of patients is that penetration with a 22 starch-coated glove shows that the starch particles 23 can -- are found in the fallopian tubes and cervix, and 24 whether I agree -- I think the data does show that, I 25 don't know if I would say avoid. That's why I kind of</p>

<p style="text-align: right;">Page 174</p> <p>1 a -- I'm hesitating to answer your question, I'm sorry 2 about that. But, I think it's a very strong statement 3 to say avoid gloves.</p> <p>4 Q. And I was just asking you what the authors --</p> <p>5 A. Oh, okay. Sorry. They stated that in their discussion. 6 Yes, they state that.</p> <p>7 Q. And the authors thought that this study was relevant to 8 whether harmful substances could be introduced to the 9 vagina, agreed?</p> <p>10 A. So I guess if we re-read that, it says, Might gain 11 access. So they used the word, is that -- again, is 12 that the sentence, so it might gain access?</p> <p>13 Q. Where are you reading at?</p> <p>14 A. The last -- oh, maybe I'm not on the right -- oh, sorry, 15 I'm at the last sentence of the introduction.</p> <p>16 Q. Well, that's before they did their study, correct?</p> <p>17 A. Yes. Sorry. Where was your -- the sentence you were 18 reading from?</p> <p>19 Q. I was reading the conclusion in the abstract. And we 20 can go ahead --</p> <p>21 A. Yeah, I think that -- sorry, I think that powder or any 22 other potentially -- that -- that sentence there?</p> <p>23 Sorry. The consequently powder or any other potentially 24 harmful, that sentence?</p> <p>25 Q. Yes.</p>	<p style="text-align: right;">Page 176</p> <p>1 gyn exam, we now have to have -- have to ask the patient 2 whether they want another person in the room because of 3 that.</p> <p>4 Q. Is intercourse forceful in some way?</p> <p>5 A. I'm not -- I'm sorry, I don't know how this is relevant, 6 but it depends, I guess.</p> <p>7 Q. Okay. Fair enough.</p> <p>8 All right. Back to your report. Under the 9 heading, Talc Particles Cannot Travel to the Fallopian 10 Tubes, and Precursor Lesions, you're just -- that's 11 basically the same as probably in the fallopian tubes, 12 correct?</p> <p>13 A. Yes, because that's where the precursor -- yes, the 14 precursor lesions are present in those tubes.</p> <p>15 Q. Yes. If present, right?</p> <p>16 A. You said if present?</p> <p>17 Q. If the precursor lesions are present.</p> <p>18 A. Yes.</p> <p>19 Q. And you mentioned these studies were conducted under 20 artificial conditions. What are those artificial 21 conditions you're referring to?</p> <p>22 A. Oh, well, I guess, if you go to that previous study, I 23 think the one where they had the women, like, lay on 24 their backs for long periods of time, or I think with 25 the -- are we talking about the human studies now,</p>
<p style="text-align: right;">Page 175</p> <p>1 A. And you're asking me if I agree that they wrote that 2 there, or if I agree with it?</p> <p>3 Q. Yeah, yes.</p> <p>4 A. Yes to which part of my question?</p> <p>5 Q. That's what the authors concluded, correct?</p> <p>6 A. If they wrote it there, I guess they concluded that, 7 yeah.</p> <p>8 Q. Okay. And my follow-up question was, the authors at 9 least thought the findings in this study were relevant 10 to harmful substances that could potentially ascend to 11 the reproductive tract to the ovaries, right?</p> <p>12 A. Using a glove that penetrates the vagina, so yeah, using 13 their technique, yes.</p> <p>14 Q. Well, the -- to be clear, the glove enters the vagina, 15 it doesn't penetrate the vagina?</p> <p>16 A. Well, but you have to -- but you have the physical force 17 to go up the vagina. It's not like you're putting on 18 your underwear, so you have to actually enter the 19 vagina.</p> <p>20 Q. And it's opinion that a glove introduced in the vagina 21 is a force, forceful entry?</p> <p>22 A. I've been to gyn visits, and I think -- I mean, it 23 depends. Some women find it very uncomfortable. And 24 actually, nowadays, you have to have a -- gynecologists 25 have to ask the patient whether they -- when they give a</p>	<p style="text-align: right;">Page 177</p> <p>1 still? Yeah.</p> <p>2 Q. Oh, we can talk about human or animal. Human, I think, 3 are more relevant to artificial conditions.</p> <p>4 A. Yeah.</p> <p>5 Q. Monkeys would be more artificial, I believe.</p> <p>6 A. Yes. So I think with the human studies we just spoke 7 about, I believe in those studies, the way they 8 conducted, I think the women were given the tracers and 9 they had to lay on their back for a certain period of 10 time, for two hours, yeah. And they had -- oh, yeah, 11 then they had to, like, cover the vulva with a sanitary 12 towel, their legs were pressed together to prevent the 13 radionucleotide from streaming out the vagina. So you 14 know, it's not typical that you're going to be sitting 15 there like that. So, you know, that's when I mention 16 artificial conditions. And I think, if we go, if I 17 remember the previous one. I guess also, like, the 18 placement of it, I guess, I was just mentioning with the 19 glove, if we're talking about placement of talc, how 20 it's usually just powder on, you're not penetrating 21 the -- the talc is not on a glove and you're not putting 22 it into your vagina, so that's why when I said 23 artificial conditions that's what I was referring to.</p> <p>24 Q. Okay. I understand, you can correct me, do women lay on 25 their backs?</p>

<p style="text-align: right;">Page 178</p> <p>1 A. Yes, they do.</p> <p>2 Q. Is oxytocin part of the physiologic hormone production</p> <p>3 that happens in human women?</p> <p>4 A. Yes. It's typically there's more often during</p> <p>5 pregnancy, during contractions.</p> <p>6 Q. Is oxytocin produced as part of the normal cycle in</p> <p>7 women?</p> <p>8 A. Yes.</p> <p>9 Q. Or do you know?</p> <p>10 A. I do. I mean, again, I work in ovarian cancer, I'm not</p> <p>11 a general gynecologist. And also, given that I work on</p> <p>12 high-grade serous ovary where hormonal contributions or</p> <p>13 oxytocin is not a main player in the pathogenesis of</p> <p>14 ovarian cancer, especially high-grade serous ovarian</p> <p>15 cancer, that's not the area of expertise because of the</p> <p>16 contributions to high-grade serous cancer. But --</p> <p>17 Q. Would you defer to a gynecologist or endocrinologist for</p> <p>18 that discussion?</p> <p>19 A. It depends on what I'm -- what questions I have about</p> <p>20 it.</p> <p>21 Q. And how and when oxytocin are produced in a woman?</p> <p>22 A. Yeah, I mean, again, I reviewed it in the past in terms</p> <p>23 of the cycle and menstrual cycles and regulatory cycles,</p> <p>24 but I haven't reviewed it in a very long time. And I</p> <p>25 have not looked at it in reference to this report, so I</p>	<p style="text-align: right;">Page 180</p> <p>1 that. I don't think that's right.</p> <p>2 Q. Is it your opinion that one needs data for everything?</p> <p>3 A. When -- I'm sorry. Go ahead.</p> <p>4 Q. I mean, do you need data that your hair grows?</p> <p>5 A. No, but there is data that your hair grows. But when</p> <p>6 we're talking about something as serious as what causes</p> <p>7 ovarian cancer, yes. Because it's like -- it's what I'm</p> <p>8 passionate about. So for that I think we -- it is</p> <p>9 critical.</p> <p>10 Q. What is pelvic organ prolapse?</p> <p>11 A. Pelvic what?</p> <p>12 Q. Pelvic organ prolapse?</p> <p>13 A. Oh, yeah. So pelvic organ prolapse -- actually, a lot</p> <p>14 of my colleagues work on another -- the chair of ob-gyn</p> <p>15 works on that. It happens quite a bit, especially in</p> <p>16 women after pregnancy. Is that what you're asking</p> <p>about? Yeah.</p> <p>18 Q. Yes.</p> <p>19 A. So -- yeah. So unfortunately, it happens in a lot of</p> <p>20 women. And it's when the pelvis, the muscles of the</p> <p>21 pelvis become weak, and then you get kind of, like,</p> <p>22 rectal prolapse, similar concept, and then you have to</p> <p>23 get surgical correction for it.</p> <p>24 Why -- I don't -- why are you asking?</p> <p>25 Q. Well, my question is, can the vagina be exposed to the</p>
<p style="text-align: right;">Page 179</p> <p>1 don't want to speak out of turn or speak incorrectly. I</p> <p>2 don't -- it's not something I've looked at recently.</p> <p>3 Q. What is the angle of the vagina?</p> <p>4 A. Are you asking me the exact degrees?</p> <p>5 Q. Approximately.</p> <p>6 A. I don't know. I don't know exact degree angle.</p> <p>7 Q. Would you defer to a gynecologist or a female anatomy</p> <p>8 specialist?</p> <p>9 A. If I needed, that -- actually, if I needed to know that,</p> <p>10 yes, I think that's who I would ask. I would ask my</p> <p>11 very great colleagues and collaborators that I work with</p> <p>12 very often.</p> <p>13 Q. Dr. Seinz, do you know who Dr. Seinz is?</p> <p>14 A. I don't recall, no.</p> <p>15 Q. I'll just let you know, she's a gynecologic oncologist</p> <p>16 that is an expert witness for Johnson & Johnson, she's</p> <p>17 testified that intercourse could push the talc particles</p> <p>18 from the perineum into the vagina and beyond, would you</p> <p>19 have any reason to disagree with her on that point?</p> <p>20 A. I don't -- so, again, I don't -- I have not explored</p> <p>21 that research. I don't know if that research has ever</p> <p>22 been performed. It would literally -- that's just a</p> <p>23 speculation. And I base my opinions on data. To state</p> <p>24 something or make a comment on that would be incorrect.</p> <p>25 And I don't feel comfortable even making a statement on</p>	<p style="text-align: right;">Page 181</p> <p>1 external environment if a woman has pelvic organ</p> <p>2 prolapse, or do you know?</p> <p>3 A. So I don't recall reading any literature about talc and</p> <p>4 the exposure to vagina -- pelvic prolapse. Remember, I</p> <p>5 did look at all the literature on talc and ovarian</p> <p>6 cancer incidents and mechanism, and there was no</p> <p>7 association with pelvic prolapse or may have -- I don't</p> <p>8 recall. And I don't know any of these studies that</p> <p>9 looked at exposure with pelvic prolapse.</p> <p>10 Q. And you didn't look at epidemiology studies, you've</p> <p>11 testified to that before, correct?</p> <p>12 A. No. I said I perused the studies, the epidemiological</p> <p>13 studies, and I was aware of the studies given my many</p> <p>14 years working in ovarian cancer. I didn't take a deep</p> <p>15 dive and look at all the statistical analysis that was</p> <p>16 done for the epidemiological studies.</p> <p>17 Q. How many case control studies are there regarding talc</p> <p>18 and its relationship with ovarian cancer?</p> <p>19 A. As I just -- given that I didn't take a deep dive into</p> <p>20 all the statistical analysis done for the</p> <p>21 epidemiological studies, I couldn't answer the question</p> <p>22 of how many case control studies were done.</p> <p>23 Q. How many cohort studies have been done?</p> <p>24 A. As I just mentioned, I don't know the specifics of the</p> <p>25 number of cases and control studies that were done.</p>

<p style="text-align: right;">Page 182</p> <p>1 Given that I perused the literature on the 2 epidemiological studies, what I can say is that from the 3 review that I did do, what I did see, and all the 4 reviews that I read and the editorials that I read, what 5 was clear is that there's contradictory data on the 6 association and the epidemiological research on talc and 7 the association with ovarian cancer.</p> <p>8 Q. What review studies were those?</p> <p>9 A. I tried to include the few in the materials that were 10 provided. And again, if -- over the last 20 years, 11 several of them I perused, so I don't remember off the 12 top of my head.</p> <p>13 Q. Can you point me to any epidemiology study that would 14 give your opinion that talcum powder does not cause or 15 contribute to the development of ovarian cancer?</p> <p>16 A. Off the top off my head, I don't remember the author's 17 name. But we can look in my report -- I don't remember 18 if I referenced it in my report.</p> <p>19 Q. Was it Fiume -- F-I-U-M-E?</p> <p>20 A. I don't recall. If we want to go through, like I said, 21 there's many. But actually, I think we can -- given 22 that I didn't do a -- include a lot of the 23 epidemiological studies in my report, I don't know if I 24 included it, but there were numerous. And also given, 25 if you look at, like, the NCCN guidelines or ACS, you</p>	<p style="text-align: right;">Page 184</p> <p>1 don't recall what information and data they base that 2 recommendation on. If we could pull that up, that would 3 be great.</p> <p>4 Q. And it's your experience as a cancer biologist doing 5 translational research that gives you that expertise?</p> <p>6 A. Yes. And being able to critically analyze and review 7 data, being a critical reviewer for the NIH and NCI and 8 American Cancer Society for over 15 years. I think 9 having the NIH ask me to review --</p> <p>10 Q. Also --</p> <p>11 A. Oh, sorry. Having the NIH ask me review grants for 12 them.</p> <p>13 Q. Are you aware --</p> <p>14 MS. SHARKO: Wait, wait. Just finish your 15 answer.</p> <p>16 MS. THOMPSON: Sorry. She was breaking up. I 17 didn't even hear last part.</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. Go ahead and finish.</p> <p>20 A. So you're asking about the expertise. I mean, having 21 the NIH ask me to review proposals over the last 22 15 years, and grants for them, provides -- justifies the 23 expertise I have in that -- in that area.</p> <p>24 Q. You're aware that there are researchers in epidemiology, 25 epidemiologists that actually work at NIH and NCI,</p>
<p style="text-align: right;">Page 183</p> <p>1 know, they also kind of -- they mention the 2 contradictory reports on talc and in there they 3 reference the studies that show no association and the 4 studies that show an association, and that's very 5 helpful in showing both sides, and I don't know exactly 6 the authors of those publications.</p> <p>7 Q. Okay. If we have time, we'll come back to some of 8 those, but I want to make sure we cover all the topics 9 in your report first.</p> <p>10 One more question on the migration issue. You 11 reviewed the FDA response to a certification in 2014, 12 correct? It's on your Materials Considered list.</p> <p>13 A. I vaguely remember looking at that. FDA.</p> <p>14 Q. The FDA states, The potential for particulates to 15 migrate from the perineum and vagina to the perineum 16 cavity is indisputable.</p> <p>17 Do you disagree with the FDA?</p> <p>18 A. Yes.</p> <p>19 Q. And what expertise do you have that allows you to 20 disagree with the FDA on that issue?</p> <p>21 A. Well, I mean, I think I've been telling you for the last 22 several hours, my expertise in ovarian cancer for the 23 last 20 years and critically analyzing the data that 24 explored whether talc can migrate to fallopian tubes or 25 ovary in both humans and primate and mouse models, and I</p>	<p style="text-align: right;">Page 185</p> <p>1 agreed?</p> <p>2 A. Oh, yes.</p> <p>3 Q. And are you aware that some of those would disagree with 4 your opinions in this case?</p> <p>5 A. I don't -- I'm not -- I haven't looked at that. I don't 6 speak to -- I don't speak to all scientists, so I don't 7 know.</p> <p>8 Q. Well, we'll maybe look at one of those later, or more. 9 If you'll turn to page 29 of your report. And 10 this begins your discussion of cell studies, agreed?</p> <p>11 A. The -- yeah, the part -- Section C?</p> <p>12 Q. Yeah, Section C. And I want to ask you some questions 13 about -- first of all, does talc in human tissue, and 14 then we'll also talk about talc in some cultures. 15 Did you look at the Mostafa study?</p> <p>16 A. Sorry, I didn't -- which study?</p> <p>17 MS. THOMPSON: Let's go ahead and, Laura, pull 18 Mostafa -- M-O-S-T-A-F-A.</p> <p>19 DEPOSITION EXHIBIT 15</p> <p>20 S.A.M. Mostafa Paper -</p> <p>21 Foreign Body Granulomas in Normal Ovaries</p> <p>22 WAS MARKED BY THE REPORTER</p> <p>23 FOR IDENTIFICATION</p> <p>24 BY MS. THOMPSON:</p> <p>25 Q. Does this look familiar?</p>

<p style="text-align: right;">Page 186</p> <p>1 A. Yes, once I see it. 2 Q. I couldn't hear you, sorry? 3 A. Oh, yes, yes. Sorry. 4 Q. And this paper was published in 1985, correct? 5 A. Yes. 6 Q. And the conclusions by this author are that particles 7 were found in the ovaries of non-ovarian cancer 8 patients, but demonstrated evidence of chronic 9 inflammation with talc granules, is that correct? 10 A. I think we need to step back. Can you repeat your 11 question? 12 Q. Let me ask my next question. 13 Does this study demonstrate that talc found in 14 ovaries is not inert? 15 A. No. 16 Q. Does this study support your opinion that talc found in 17 ovaries does not produce a biological effect? 18 A. So what this steady simply shows is that they found 19 particles, foreign particles that might -- may be 20 consistent with talc, based on x-ray analysis in 21 granulomas. It's a very descriptive study. 22 Q. What's your opinion as to how the talc got to the 23 ovaries? 24 A. I don't know if it's even talc, so I can't comment. 25 Q. What's your opinion as to how the particles got to the</p>	<p style="text-align: right;">Page 188</p> <p>1 what you're asking me. Whether talc can form a 2 granuloma. But this data's not -- doesn't show that 3 talc can cause a granuloma. 4 Q. Well, do you know who Dr. Woodruff is, one of the 5 authors on this paper? 6 A. No. 7 Q. Dr. Woodruff is considered to be the father of 8 gynecologic pathology, and probably the best known GYN 9 pathologist in the world. And he described talc 10 granulomas in ovaries removed for benign disease. And 11 you're saying that you think this is contamination on 12 talc at the laboratory. My question is, how do you form 13 a talc granuloma between the time a specimen gets to the 14 laboratory and when it's looked at under a microscope? 15 It's a pretty simple question. 16 A. There is no evidence that you can form a talc granuloma, 17 therefore, I cannot answer your question. 18 Q. I don't understand that answer, but we'll move on. 19 MS. THOMPSON: Let's pull Wehner, the second 20 Wehner paper, which is Biological Effects of Cosmetic 21 Talc. 22 DEPOSITION EXHIBIT 16 23 A.P. Wehner Paper - Biological 24 Effects of Cosmetic Talc 25 WAS MARKED BY THE REPORTER</p>
<p style="text-align: right;">Page 187</p> <p>1 ovaries that the authors conclude are talc or -- 2 A. I think it might be -- number one, it might be 3 contamination. So working in a pathology lab -- 4 Q. Okay. How do you find -- 5 A. I'm -- 6 MS. SHARKO: She wasn't -- 7 MS. THOMPSON: And I'm going to try to move 8 along because my time is short, so again, I'm not trying 9 to interrupt you. 10 THE WITNESS: Oh, sorry. Well, I think it's 11 important, though. Because working in a pathology lab, 12 these type of studies -- and that's why I mention the 13 descriptiveness of it -- there's a lot of contaminants. 14 We get lot of anatomical specimens, there's a lot of 15 chemical compounds, you know, and those I don't comment 16 on, but it's -- these foreign bodies appear. And having 17 reproducible data is important. So that's why I don't 18 want to make these bold statements and say yes to your 19 answers because I can't confirm otherwise whether these 20 are true results, so I don't know what the particles 21 are. 22 BY MS. THOMPSON: 23 Q. Can talc cause a granuloma between when it gets to the 24 lab and when it gets examined in the microscope? 25 A. I don't -- I don't know -- I don't know. I don't know</p>	<p style="text-align: right;">Page 189</p> <p>1 FOR IDENTIFICATION 2 BY MS. THOMPSON: 3 Q. And this is another Wehner paper, and this time 4 Dr. Wehner does disclose that this paper is based on a 5 critical literature review previously prepared for 6 Johnson & Johnson. Do you see that the disclosure after 7 conclusion? And I just want to ask you about two 8 things that -- or three things that Dr. Wehner says in 9 this paper and see if you agree. 10 On page 1179, under Talc Granulomas from 11 Powdered Surgical Gloves. 12 A. Okay. 13 Q. Are you there? 14 A. Yes. 15 Q. Dr. Wehner states that, Talc powder is fibrogenic. 16 Do you agree with that statement? 17 A. I have not reviewed the article on whether -- I'm not 18 quite sure exactly. I don't -- I can't agree or 19 disagree with that comment. I'm sorry. 20 Q. Okay. So this statement doesn't have to be from Wehner 21 paper, but it happens to be, Talc powder is fibrogenic 22 when administered by various routes to many species of 23 animals. 24 Do you agree with that statement based on your 25 review of this case?</p>

<p style="text-align: right;">Page 190</p> <p>1 A. Fibrogenic. I did not review the literature on its 2 fibrogenicity, and I'm not -- 3 Q. Well, you've reviewed the -- 4 A. So -- go ahead. 5 Q. Can something be fibrogenic and inert at the same time? 6 A. Again, I don't -- so the reference to this Lord, 1978 7 paper, is that one of the ones we've talked about? So I 8 want to -- 9 Q. It's in front of you, right? 10 A. The Lord -- no. The paper that it references to say 11 that it's fibrogenic? 12 Q. No. Well, Dr. Wehner says it's fibrogenic, right? 13 A. I could say anything, no one's going to believe me, 14 right? So I have to see the data. 15 Q. Okay. 16 A. Sorry. 17 Q. Well, I do not have the Lord paper. 18 So you would not trust a J&J consultant who 19 did an extensive safety review for Johnson & Johnson 20 when he states that talcum powder is fibrogenic. 21 A. I did not -- 22 Q. You would have to see the original data? 23 A. I would want to see the data that's referenced -- 24 I need to state -- any time I'm -- a statement 25 is made, as I mentioned many times, I like to go back</p>	<p style="text-align: right;">Page 192</p> <p>1 patient with a pleural effusion? 2 A. No. Again, I didn't review that literature for this 3 case, and I don't work in pleural eff -- no. 4 Q. And on page 1181, Dr. Wehner states, Talc is a 5 recognized fibrogen, on the last paragraph under 6 Discussion, second column before Talc Inhalation. 7 A. Okay. One second. So -- 8 Q. And it's not cited. Would you have to ask Dr. Wehner 9 how he came to that opinion -- 10 A. Sorry. I'm not sure -- 11 Q. -- that talc is a recognized fibrogen. 12 A. I think I'm going to reiterate what I mentioned, I 13 don't -- I didn't look at the fibrogenic properties of 14 talc. I looked at the carcinogenic properties and 15 whether it's transformative. So regardless of whether 16 something's referenced here, I can't speak to the 17 fibrogenic properties of talc without reviewing the 18 literature and the data and the experiments that were 19 done to prove that it's fibrogenic. 20 Q. And you would agree that fibrogenicity would be 21 biological activity in tissues? 22 A. Yeah. I mean, I guess fibrosis is a biological output 23 if it has that fibrotic effect it causes -- but -- yeah, 24 it's a biological output. 25 Q. Activity?</p>
<p style="text-align: right;">Page 191</p> <p>1 and look at the raw data if I'm going to make a 2 statement. That's all I said. So if you want to pull 3 up the paper that's referenced, I'll be happy to make a 4 comment. 5 Q. Whether talc has a biological effect in tissues is a 6 central concept in this case, would you agree? 7 A. No. Nothing is simple. 8 Q. I didn't say simple, I said central. 9 A. Oh, central. I thought you said simple. I'm like, I 10 wish. Central, whether it has a biol -- 11 Q. Yes. 12 A. Yeah. Central, yes. It's central in this case, yes. 13 Q. But you're not willing to make -- to offer an opinion as 14 to whether talc powder is fibrogenic without seeing a 15 previous study published in 1978 cited by Dr. Wehner. 16 A. I cannot make a statement on a study that I have not 17 reviewed. 18 Q. And have you reviewed any of the pleurodesis literature 19 in forming your opinions in this case? 20 A. Pleurodesis. I don't think for this case I have any 21 references on that. I don't recall if I did review it. 22 I know sometimes it's in the summary of what talc is 23 used for, but I don't think I reviewed the literature on 24 that. 25 Q. So you're not aware of how pleurodesis works in a</p>	<p style="text-align: right;">Page 193</p> <p>1 A. Output, activity. Again -- yes. I don't work on 2 fibrosis. In the lung, it's a very relevant issue, 3 therefore -- but I don't work in that area, so I don't 4 want to speak to that. 5 MS. THOMPSON: Laura -- let's look at the cell 6 study next, Dr. DiFeo, and it's might be easier if we 7 just pull these together, because we're not -- I don't 8 want to go through them detail, I just want to know 9 whether they support your opinions or not. 10 Laura, that would be the Shukla -- 11 S-H-U-K-L-A, Buz'Zard -- B-U-Z-Z-A-R-D, Mandarino. 12 Emi -- E-M-I -- Saed -- S-A-E-D -- paper that's in your 13 box. 14 DEPOSITION EXHIBIT 17 15 Arti Shukla Paper - Alterations 16 in Gene Expression in Human Mesothelial Cells 17 WAS MARKED BY THE REPORTER 18 FOR IDENTIFICATION 19 BY MS. THOMPSON: 20 Q. Okay. Have you seen this study, Dr. DiFeo? 21 A. Yes. 22 Q. And this paper looked at gene expression with asbestos 23 and talc, correct? 24 A. Yes. 25 Q. Do you agree that asbestos is a known carcinogen?</p>

<p style="text-align: right;">Page 194</p> <p>1 A. Yes.</p> <p>2 Q. I didn't hear an answer.</p> <p>3 A. Yes, it is.</p> <p>4 Q. And these authors in the first paragraph in the body of</p> <p>5 the paper states that, The molecular mechanisms of</p> <p>6 asbestos-related diseases are poorly understood.</p> <p>7 Would you agree with that statement?</p> <p>8 A. Where are you -- oh. Where are you looking?</p> <p>9 Q. First paragraph, page -- first page of the body of that</p> <p>10 article.</p> <p>11 A. Molecular mechanism. So what that means -- so something</p> <p>12 could be carcinogenic, but the molecular mechanism can</p> <p>13 be unknown; meaning, that the genes that are responsible</p> <p>14 or the molecular components that drive that are unknown.</p> <p>15 However, whether it causes cancer biologically, right,</p> <p>16 is known. So that's why I said it is a carcinogen,</p> <p>17 because the biological studies have been done to show</p> <p>18 it, for instance, in mesothelioma or in lung cancer.</p> <p>19 But what they're stating here is that the molecules that</p> <p>20 are responsible for that are unknown. Like, the gene</p> <p>21 mutations that drive it are unknown. So --</p> <p>22 Q. Okay. And this paper is looking at the effects of</p> <p>23 asbestos with ovarian epithelial cell cultures, do you</p> <p>24 agree?</p> <p>25 A. So the majority of this paper, no, I don't agree with</p>	<p style="text-align: right;">Page 196</p> <p>1 pathogenic or innocuous particulates in human cells that</p> <p>2 may be targets for the development of disease remain</p> <p>3 enigmatic.</p> <p>4 Same concept?</p> <p>5 A. Yeah.</p> <p>6 Q. And so even with asbestos, a potent and known</p> <p>7 carcinogen, these authors say the mechanism is unclear,</p> <p>8 poorly understood, and enigmatic. Do you agree?</p> <p>9 MS. SHARKO: Object to the form.</p> <p>10 BY MS. THOMPSON:</p> <p>11 Q. Isn't that how the authors describe the mechanism?</p> <p>12 A. It's very different than what I state in my report in</p> <p>13 terms of talc. As I was stating --</p> <p>14 Q. I didn't ask you about your report, I'm talking about</p> <p>15 the Shukla article and what the authors say.</p> <p>16 MS. SHARKO: Dr. DiFeo --</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. Is that what the authors have stated regarding asbestos.</p> <p>19 MS. SHARKO: Well, Dr. DiFeo didn't answer</p> <p>20 your previous question. You interrupted her. I don't</p> <p>21 think you heard that she was continuing on.</p> <p>22 THE WITNESS: What I'm trying to distinguish</p> <p>23 and what I think is important what the authors are</p> <p>24 distinguishing here is that it's known that asbestos is</p> <p>25 a carcinogen, but what we don't know are the molecular.</p>
<p style="text-align: right;">Page 195</p> <p>1 that. The majority of this paper is primarily looking</p> <p>2 at mesothelial cells. And, again, getting back to what</p> <p>3 I was stating, the thing with mesothelial cells and</p> <p>4 asbestos is there are people that are exposed to</p> <p>5 asbestos and still do not develop mesothelial cancer.</p> <p>6 And that's why it's important to understand the</p> <p>7 molecular mechanism and understand why do some patients</p> <p>8 develop mesothelioma when exposed to asbestos and some</p> <p>9 patients do not. And what we know about cancer is that</p> <p>10 certain mutations arise under exposure with asbestos and</p> <p>11 certain mutations don't, or gene expression profiles,</p> <p>12 and that's what they're trying to distinguish here.</p> <p>13 Q. And the authors go on to say, Although it's widely</p> <p>14 acknowledged that fibrous geometry surface and chemical</p> <p>15 composition and durability are important features in the</p> <p>16 development of asbestos-associated diseases, how these</p> <p>17 contribute to cell toxicity and transformation are</p> <p>18 unclear.</p> <p>19 Is that what the authors state?</p> <p>20 A. Yes. So again, what they're saying is that the</p> <p>21 asbestos -- it contributes to mesothelioma or</p> <p>22 transformation, but the genetics and the genes that are</p> <p>23 responsible for that are unclear.</p> <p>24 Q. And the next sentence, Moreover, the early molecular</p> <p>25 events leading to injury by asbestos fibers and other</p>	<p style="text-align: right;">Page 197</p> <p>1 So what's important is the word molecular, the molecular</p> <p>2 mechanism. We know the biological mechanism, so we know</p> <p>3 that it causes cancer. We don't know the molecular</p> <p>4 mechanism of how it causes it. There's a huge</p> <p>5 distinction there --</p> <p>6 BY MS. THOMPSON:</p> <p>7 Q. And you're free --</p> <p>8 MS. SHARKO: Wait. Were you finished?</p> <p>9 THE WITNESS: Yeah, I just want to say,</p> <p>10 there's a huge distinction there in terms of certain</p> <p>11 things we don't know the biological mechanism or the</p> <p>12 molecular mechanism, right? In some them things we know</p> <p>13 that it's biologically relevant, but we don't know the</p> <p>14 molecular mechanism. And that's what they saying here.</p> <p>15 BY MS. THOMPSON:</p> <p>16 Q. Do you agree that this study demonstrates upregulation</p> <p>17 of the genes with talc exposure?</p> <p>18 A. I think the studies, if I recall, they took immortalized</p> <p>19 ovarian cancer epithelial cells and exposed them to</p> <p>20 non-fibrous talc and fine -- and some control titanium</p> <p>21 oxide, I believe it was. Yeah.</p> <p>22 Q. Does non-fibrous talc exist, or do you know?</p> <p>23 A. Yeah, I'm not a chemist. What I did, again, that's why</p> <p>24 I included all the experiments that were done looking at</p> <p>25 talc, and its implications in molecular and biological</p>

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<p style="text-align: right;">Page 198</p> <p>1 transformation of ovarian cancer cells, and this is one 2 study that looked at non-fibrous talc. There's other 3 studies as you'll -- maybe we'll discuss that looks at 4 other forms of talc. And here, they did look at a 5 subset of genes. So to answer your question, they look 6 at some gene expression after the exposure to talc, 7 non-fibrous talc.</p> <p>8 Q. Did the Shukla study support your opinion that talc does 9 not contribute or cause ovarian cancer?</p> <p>10 A. Yes.</p> <p>11 Q. Let's go to the Buz'Zard paper.</p> <p>12 DEPOSITION EXHIBIT 18</p> <p>13 Amber Buz'Zard Paper -</p> <p>14 Pycnogenol Reduces Talc-induced Neoplastic 15 Transformation in Human Ovarian Cell Cultures</p> <p>16 WAS MARKED BY THE REPORTER</p> <p>17 FOR IDENTIFICATION</p> <p>18 BY MS. THOMPSON:</p> <p>19 Q. And you're familiar with this paper, correct?</p> <p>20 A. Yeah. I --</p> <p>21 Q. And the authors' conclusions were that talc -- and this 22 used normal human epithelial and granulosa ovarian cell 23 lines and polymorphonuclear neutrophils, correct?</p> <p>24 A. And again, they used ovarian epithelial lines, yes. Not 25 the correct model for high-grade serous.</p>	<p style="text-align: right;">Page 200</p> <p>1 A. I have not.</p> <p>2 Q. Let's look at the Mandarino study.</p> <p>3 DEPOSITION EXHIBIT 19</p> <p>4 Angelo Mandarino Paper -</p> <p>5 The Effect of Talc Particles on Phagocytes</p> <p>6 WAS MARKED BY THE REPORTER</p> <p>7 FOR IDENTIFICATION</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. And this study used murine. That means mouse, right?</p> <p>10 A. Yeah.</p> <p>11 Q. This study found that, just reading from the abstract, 12 found that murine ovarian surface epithelial cells 13 MOSEC, a prototype of certain forms of ovarian cancer, 14 were present in larger numbers after co-culture with 15 macrophages treated to a combination of talc and 16 estradiol than to either agent alone or vehicle.</p> <p>17 I read that correctly, although I may not have 18 put the emphasis in the right place.</p> <p>19 I believe you disagree with the conclusion of 20 these authors as to their findings, am I correct?</p> <p>21 A. Yes.</p> <p>22 Q. But these authors at least said that their findings, 23 reading the last sentence of the abstract, suggest that, 24 In vitro exposure to talc, particularly in a high 25 estrogen environment, may compromise immunosurveillance</p>
<p style="text-align: right;">Page 199</p> <p>1 Q. And the authors demonstrated, according to the authors, 2 Increased proliferation or talc increased proliferation 3 induced neoplastic transformation and increased ROS 4 generation, time dependently in the ovarian cells and 5 dosed dependently in the PMN.</p> <p>6 Do you agree that that's -- were the authors 7 findings?</p> <p>8 A. That the authors state that in their discussion?</p> <p>9 Q. Yes.</p> <p>10 A. The authors state that. Do I agree with the findings, 11 no.</p> <p>12 Q. Does this study support your opinion that talc is inert?</p> <p>13 A. It's inert, yeah.</p> <p>14 Q. Does this support your opinion that talc has no biologic 15 effect?</p> <p>16 A. It supports my opinion that talc does not cause 17 neoplastic transformation of ovarian cancer cells or 18 biological effect.</p> <p>19 Q. That was going to be my next question. But the question 20 that I asked, actually asked was, does this support your 21 opinion that talc has no biological effect?</p> <p>22 A. I'm sorry, yes, it does support my opinion that it does 23 not have biological effect on these.</p> <p>24 Q. Have you tried to replicate any of these cell studies in 25 your lab with talc?</p>	<p style="text-align: right;">Page 201</p> <p>1 functions of macrophages and prompt further studies to 2 elucidate this mechanism.</p> <p>3 The compromising of immunosurveillance 4 functions is one of Hannahan's hallmarks of cancer, 5 correct?</p> <p>6 A. Yes. And --</p> <p>7 Q. And it's also one of the ten factors that were included 8 in the Smith paper for the working group of IARC, 9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Did you attempt to replicate this study?</p> <p>12 A. No. But, again, my lab works solely in ovarian cancer 13 research. These type of studies are commonly performed 14 in my lab, however, not with talc, given that there is 15 not a rationale or justification for utilizing talc as a 16 transformative factor, but we did not replicate these 17 specific studies with talc, but we do similar studies 18 with other factors that we believe induce 19 transformation.</p> <p>20 Q. And going to the last paragraph of the paper, the 21 authors conclude that --</p> <p>22 A. One second.</p> <p>23 Q. I think -- scratch that, let me --</p> <p>24 These authors are from Brown University, 25 Harvard. Is that your understanding?</p>

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<p style="text-align: right;">Page 202</p> <p>1 A. I'm sorry, I didn't look at their affiliations. Do you 2 want me to quickly look at that? I didn't look. Let's 3 see if it's on the first -- it's usually on the first 4 page.</p> <p>5 Yes, it does seem to be -- let's see. Brown, 6 Harvard, University of Rochester, one of them is PLLC. 7 Harvard. And one of them's retired. Yeah.</p> <p>8 Q. The last sentence in the paper states, Exposures of 9 macrophages to talc, and especially co-exposure to talc 10 and estradiol, has led to increased production of 11 reactive oxygen species and changes in expression of 12 macrophage genes pertinent in cancer development and 13 immunosurveillance.</p> <p>14 Do you agree with me that those are hallmarks 15 of cancer?</p> <p>16 A. So you're saying immunosurveillance. So the lack of 17 immunosurveillance is hallmark of cancer. However, 18 these studies simply show there's a difference in gene 19 expression. It does not show any biological evidence 20 that that change in gene expression affects 21 immunosurveillance. There's many genes, probably over 22 2,000 genes that are involved in immunosurveillance. 23 And whether a small increase in the gene expression 24 level of those genes can affect immunosurveillance is 25 unclear. Therefore, when you see differences in gene</p>	<p style="text-align: right;">Page 204</p> <p>1 A. Yes.</p> <p>2 Q. And this paper looked at epigenomic effects, when -- I 3 think if we're studying murine and process studies who 4 are exposed to talc, correct?</p> <p>5 A. Yes, they're the same.</p> <p>6 Q. The first sentence of the introduction, Epigenetic 7 regulation plays an important role in maturation and 8 functioning of phagocytes.</p> <p>9 Do you agree with that statement?</p> <p>10 A. Sorry. Plays an important role. Yeah. Many things do, 11 but that's one component, sure. Yes.</p> <p>12 Q. And epigenetic changes are one of the hallmarks of 13 cancer as well, correct?</p> <p>14 A. Well, it's in the criteria, yes.</p> <p>15 Q. And this paper exposed the uterine cells to talc as well 16 as titanium dioxide as a control, is that your 17 understanding?</p> <p>18 A. Sorry, did you say that it exposed the macrophages, 19 right, you said?</p> <p>20 Q. Yes, yes.</p> <p>21 A. Okay. Sorry. I just wanted to -- yes.</p> <p>22 Q. I may have just said cells, but --</p> <p>23 A. Yeah, no. It's getting late -- I was wanting to confirm 24 that, yes, the macrophages, yes.</p> <p>25 Q. And the study showed that the titanium oxide</p>
<p style="text-align: right;">Page 203</p> <p>1 expression, the downstream effects of those genes needs 2 to be assessed. So at this point, these studies are 3 simply an association. Again, it's just descriptive 4 work. There's no real indication that any of these 5 effects would have immediate implications and 6 immunosurveillance.</p> <p>7 Q. And I'm just hearing you say that you disagree with the 8 conclusions of the researchers who performed the study, 9 right?</p> <p>10 A. I disagree with the assessment of the results that these 11 results would assume that talc and estradiol can have 12 these effects, yes.</p> <p>13 MS. THOMPSON: Okay. Let's go to the next 14 exhibit.</p> <p>15 DEPOSITION EXHIBIT 20</p> <p>16 T. Emi Paper - Transcriptomic and 17 Epigenomic Effects of Insoluble 18 Particles on J774 Macrophages</p> <p>19 WAS MARKED BY THE REPORTER</p> <p>20 FOR IDENTIFICATION</p> <p>21 BY MS. THOMPSON:</p> <p>22 Q. Do you have that in front of you, Dr. DiFeo?</p> <p>23 A. I do. I do.</p> <p>24 Q. And you reviewed that Emi paper, and I think discussed 25 it in your report, correct?</p>	<p style="text-align: right;">Page 205</p> <p>1 particles -- I'm in a thunderstorm here, so I'll try to 2 talk a little more loudly, but if you can't hear or 3 understand me, let me know and I'll see what I can do 4 about that, other than stop the rain.</p> <p>5 Okay. Back to my question. The study found 6 changes with both the inert particles or presumed inert 7 particles, titanium oxide, as well as the talc 8 particles, is that correct?</p> <p>9 A. Yes. They --</p> <p>10 Q. But the effects from the talc were more significant, do 11 you agree?</p> <p>12 A. I think we need to -- if we go through the paper, I 13 think it's important to see what effects we're 14 discussing.</p> <p>15 Q. Okay. Let's look at -- my pages aren't numbered, but 16 let's go to the Discussion section.</p> <p>17 And there's a paragraph on the second page of 18 the discussion section that begins with, Pathway 19 analysis, if you can find that.</p> <p>20 A. Hold on one second. In the discussion, the second 21 paragraph?</p> <p>22 Q. It's the third-to-the-last page of the paper, towards 23 the end of the discussion section and the paragraph 24 begins with, Pathway analysis.</p> <p>25 A. Oh, I see. Okay.</p>

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<p style="text-align: right;">Page 206</p> <p>1 Q. It's on the bottom of mine, I think, if we have the same 2 paper. 3 A. No. I think - it's on the top of page 1068 for me. 4 Okay. 5 Q. Okay. I think I have a --- 6 A. I've got it. 7 Q. I've got the manuscript rather than the actual paper. 8 But the sentence says, Pathway analysis has 9 identified that the pathway affected by talc included 10 cell proliferation, immune responses and signaling, 11 immuno surveillance, and apoptosis. 12 That's the authors' conclusion, correct? 13 A. Yeah. Typically, that's what you write in the 14 discussion is what you interpret from your results, so I 15 believe that's their conclusion. 16 Q. Correct. Understood. And you would agree that those 17 are some of the effects that we saw in Hannahan and that 18 we saw in the Smith paper on the carcinogenic factors, 19 would you -- 20 A. I believe so. These are very common pathways that come 21 up. 22 Q. And does the Emi paper conclude that talc is inert? 23 A. It's interesting, because they don't actually state that 24 it's not inert, and from this data, they just describe 25 the gene, the difference in pathway analysis and gene</p>	<p style="text-align: right;">Page 208</p> <p>1 Ghassan M. Saed Paper 2 WAS MARKED BY THE REPORTER 3 FOR IDENTIFICATION 4 BY MS. THOMPSON: 5 Q. Are you looking at this paper? 6 A. Now I have it, yep. 7 Q. I can't tell when I'm -- 8 A. Sorry about that. Yes, yes. 9 Q. Have you seen this paper before? 10 A. This one is -- which one is this one now? Oh, this is 11 the comment -- the review, I think. Yeah, bursa. Oh, 12 yeah, it's -- yeah. 13 Q. And this was published in 2017 in Gynecologic Oncology? 14 A. Oh, wait, no. I have -- sorry. I think I'm looking at 15 a different one. I'm looking at the 2014 prospective 16 paper. I think there's another Saed paper. 17 MS. THOMPSON: Okay. You may have the -- 18 THE WITNESS: Yeah, I have the prospective 19 one. Yeah. 20 DEPOSITION EXHIBIT 21 21 Ghassan M. Saed - Updates of the 22 Role of Oxidative Stress in the 23 Pathogenesis of Ovarian Cancer 24 WAS RE-MARKED BY THE REPORTER 25 FOR IDENTIFICATION</p>
<p style="text-align: right;">Page 207</p> <p>1 expression. And that's all you can say. It's a very 2 descriptive data. And from their discussion, they don't 3 make any overall, bold, definitive statements because 4 you can't. And if you look at the figures, there's just 5 a lot of pathway analysis. Pretty much every pathway 6 comes up. And when you do these pathway analysis 7 assessments, you can almost get any pathway to come up 8 if you don't filter your data. And that's what it seems 9 like they get. You can clearly see that, especially on 10 Figure 12, you get almost every gene significantly 11 altered. And I think that's why it's really hard for 12 them, and it's clear when you read this discussion, to 13 make very definitive statements on what pathways it's 14 modifying. So biological relevance and whether it's not 15 inert cannot be stated. And I don't think they clearly 16 state it even in their discussion. 17 Q. Does this support your opinion that talc does not 18 contribute or cause ovarian cancer? 19 A. It does not, yeah. This paper further supports that it 20 does not. 21 Q. Okay. Let's go to the Saed paper, and then we'll take a 22 break if that's good timing. 23 MS. THOMPSON: Let's mark the Saed paper as 24 exhibit next. 25 DEPOSITION EXHIBIT 21</p>	<p style="text-align: right;">Page 209</p> <p>1 BY MS. THOMPSON: 2 Q. Have you seen this paper, Dr. DiFeo? 3 A. Yeah, is it Updates of the Role of Oxidative Stress in 4 the Pathogenesis of Ovarian Cancer? 5 Q. Yes. Have you seen this comparison before? 6 A. Yes. Yeah. 7 Q. Okay. And this is published in Gynecologic Oncology, 8 which is the publication of the Society for Gynecologic 9 Oncologists, correct? 10 A. Yes. 11 Q. And this was an invited review article, is that your 12 understanding? 13 A. I don't know if it was invited or not. I can't make 14 that conclusion, whether it was invited or submitted 15 review. 16 Q. If it's invited, the journal typically chooses someone 17 who has expertise in the subject matter, correct? 18 A. Yeah. If it's invited. I just said I don't know if it 19 was invited or -- because, typically, you can also just 20 submit a review article and then it gets peer-reviewed. 21 Q. Agree. And it's not clear from this paper, so we'll 22 just look at the contents of the paper itself now. 23 Is there anything in the review article for 24 Dr. Saed from 2017 that you disagree with? 25 A. I mean, this is a really long article. I don't --</p>

53 (Pages 206 - 209)

<p style="text-align: right;">Page 210</p> <p>1 MS. SHARKO: She's not asking you to identify 2 everything you disagree with, she just wants to know if 3 you disagree with what's in it.</p> <p>4 MS. THOMPSON: If you want to look at it and 5 go off the record --</p> <p>6 THE WITNESS: Oh, I thought you wanted me to 7 go through and look at everything.</p> <p>8 I think the overall, if I recall, because I 9 don't remember everything he states in here, because 10 it's a review article that goes through everything, but 11 I think, overall, I disagree with the fact that talc has 12 a biological significance and that it plays a role in 13 ovarian cancer pathogenesis.</p> <p>14 BY MS. THOMPSON:</p> <p>15 Q. But there's no mention of talc in this article, correct?</p> <p>16 A. I don't -- I thought there -- I thought that there was. 17 See, that's why I wanted to take a second. Sorry if I 18 may have misspoke. I don't -- that's why I wanted to 19 take a second for look through it.</p> <p>20 MS. THOMPSON: Laura, let's just go off the 21 record and you can have some time to look at this 22 article.</p> <p>23 (A short recess was taken)</p> <p>24 BY MS. THOMPSON:</p> <p>25 Q. My only question on the Saed paper is, do you agree with</p>	<p style="text-align: right;">Page 212</p> <p>1 factors, inflammation is an important risk factor for 2 ovarian cancer.</p> <p>3 That paper's no longer reliant to this, is it?</p> <p>4 A. I'm just looking at the paper now. One second.</p> <p>5 Q. I'm going to have you take my word for it so we can get 6 through these, and if you find it, we can come back and 7 correct the record.</p> <p>8 The Savant paper says, Inflammation plays a 9 role in the initiation and development of many types of 10 cancer, including epithelial ovarian cancer and 11 high-grade serous ovarian cancer.</p> <p>12 The Savant paper is not on your reliance list, 13 is it?</p> <p>14 A. (No response.)</p> <p>15 Q. The Shan-Lu paper says, Increasing evidence suggests 16 that inflammation contributes significantly to the 17 etiology of EOC.</p> <p>18 That paper is not on your list is it?</p> <p>19 A. I'm sorry, you're talking about a Savant paper. I don't 20 that paper in front of me.</p> <p>21 Q. Shan-Lu? I'm asking if it's on your reliance list.</p> <p>22 A. I thought it was Savant. I didn't memorize -- I don't 23 know --</p> <p>24 MS. SHARKO: Wait.</p> <p>25 THE WITNESS: -- all the first author names,</p>
<p style="text-align: right;">Page 211</p> <p>1 anything in that 2017 Saed paper?</p> <p>2 A. Yeah. I know, it's a review of oxidative stress and the 3 pathogenics of ovarian cancer. You know, I -- it's a 4 review, so I didn't really go in depth in analyzing it, 5 and a lot of work is referenced and by respective 6 colleagues in the field, so I don't disagree with any of 7 the statements.</p> <p>8 MS. SHARKO: You don't agree or you don't 9 disagree with any statements?</p> <p>10 THE WITNESS: I don't -- I agree with the 11 majority of the statements made in this review.</p> <p>12 MS. THOMPSON: Okay. Let's take a break and 13 then we'll come back and go through the inflammation 14 papers briefly.</p> <p>15 MS. SHARKO: Okay.</p> <p>16 (A short recess was taken)</p> <p>17 BY MS. THOMPSON:</p> <p>18 Q. Dr. DiFeo, it's your opinion that inflammation does not 19 appear to play a role in ovarian cancer, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you did a search of the literature relating to 22 inflammation in an ovarian cancer, correct?</p> <p>23 A. Yes.</p> <p>24 Q. The Sanchez-Prieto paper states, among other factors, 25 such as hereditary, environmental, and lifestyle</p>	<p style="text-align: right;">Page 213</p> <p>1 sorry. I can look at that. Sorry. You said Savant -- 2 S-A-V-A-N-T?</p> <p>3 BY MS. THOMPSON:</p> <p>4 Q. Correct. The next one was Shan -- S-H-A-N.</p> <p>5 A. No. I don't have that one.</p> <p>6 Q. The Trabert paper states, Epidemiologic evidence 7 implicates chronic inflammation as a central mechanism 8 in the pathogenesis of ovarian cancer, the most lethal 9 gynecologic cancer among women in the United States.</p> <p>10 The Trabert paper is not on your reliance 11 list, is it?</p> <p>12 A. So --</p> <p>13 MS. SHARKO: I object to the form of the 14 question. The witness hasn't been given the Trabert 15 paper. Do you want her to verify what you're saying and 16 discuss it or do you just want to know if it's on her 17 reliance list?</p> <p>18 MS. THOMPSON: I just want to know if it's on 19 her reliance list.</p> <p>20 BY MS. THOMPSON:</p> <p>21 Q. The Breger paper states --</p> <p>22 MS. O'DELL: Margaret, I didn't hear an answer 23 if she responded to Trabert.</p> <p>24 MS. SHARKO: The question is, is that paper by 25 Trabert on your reliance list, Dr. DiFeo. If you can</p>

<p style="text-align: right;">Page 214</p> <p>1 check that, please.</p> <p>2 THE WITNESS: I'm sorry. No, that is not.</p> <p>3 But again, I'm just look at the -- this paper is an</p> <p>4 epidemiological paper looking at inflammatory markers.</p> <p>5 It's an association paper. Not looking at the</p> <p>6 mechanistic role of inflammation in the pathogenesis of</p> <p>7 ovarian cancer.</p> <p>8 BY MS. THOMPSON:</p> <p>9 Q. Okay. I'm just asking you whether these papers are on</p> <p>10 your reliance list. The Breger paper --</p> <p>11 MS. THOMPSON: And we can send that to you in</p> <p>12 the chat, Laura.</p> <p>13 BY MS. THOMPSON:</p> <p>14 Q. -- states that chronic inflammation can directly cause</p> <p>15 DNA damage, with his particularly relevant for cancer</p> <p>16 initiation and progression.</p> <p>17 Is the Breger -- B-R-E-G-E-R -- article on</p> <p>18 your reliance list?</p> <p>19 MS. SHARKO: Again, I object to the form of</p> <p>20 the question and the preface. And the witness does not</p> <p>21 have the Breger paper in front of her. I guess if you</p> <p>22 spell the author's name, she could --</p> <p>23 MS. THOMPSON: I can send the exhibit to you</p> <p>24 in the chat. But I'm just asking her if it's on her</p> <p>25 reliance list. We can retract.</p>	<p style="text-align: right;">Page 216</p> <p>1 some of Permuth's report. Yeah, that's the ones that I</p> <p>2 really remember.</p> <p>3 Q. Did you rely on any of those expert reports in</p> <p>4 formulating your opinions provided in the expert report?</p> <p>5 A. Oh, no. No.</p> <p>6 Q. Are all the opinions that you intend to give at trial</p> <p>7 contained in your expert report or given in answers to</p> <p>8 my questions at this deposition?</p> <p>9 A. Well, I don't know if I'm going to be asked to testify</p> <p>10 at trial, but I will answer the same as I'm answering</p> <p>11 today.</p> <p>12 Q. But you're not planning on offering opinions that I</p> <p>13 don't know about?</p> <p>14 A. Offering -- sorry, that I don't -- that you -- that I</p> <p>15 don't know about?</p> <p>16 Q. That we haven't talked about today or are included in</p> <p>17 your expert report.</p> <p>18 A. I don't know what I'm going to be asked at trial. I</p> <p>19 can't state what I'm going to talk about. I don't know.</p> <p>20 Q. You're not planning to give opinions regarding the</p> <p>21 individual plaintiffs, correct?</p> <p>22 A. Again, I don't know what I'll be asked at trial. I</p> <p>23 don't -- I'm not familiar with the process.</p> <p>24 Q. Well, this is my opportunity today to know what your</p> <p>25 opinions are, and if you intend to be offering different</p>
<p style="text-align: right;">Page 215</p> <p>1 BY MS. THOMPSON:</p> <p>2 Q. Okay. Dr. DiFeo, if we could go to your materials</p> <p>3 reviewed and considered list to page 16.</p> <p>4 A. Sorry.</p> <p>5 Q. And on page --</p> <p>6 MS. SHARKO: Wait, wait, wait. Let's just get</p> <p>7 the document up, please. Do you have it?</p> <p>8 THE WITNESS: This one?</p> <p>9 MS. SHARKO: Exhibit 3.</p> <p>10 THE WITNESS: Okay.</p> <p>11 MS. SHARKO: Okay. Go ahead.</p> <p>12 BY MS. THOMPSON:</p> <p>13 Q. Beginning on page 16, which is Reports and Depositions,</p> <p>14 Documents and Medical Records, you mentioned you didn't</p> <p>15 have time to review all of those. Can you tell me the</p> <p>16 ones that you did review? If you can.</p> <p>17 A. Yeah. So given that I was -- I hadn't really -- it's my</p> <p>18 first time writing an expert report, I reviewed, I</p> <p>19 believe -- and again, I can't remember all of them. I</p> <p>20 perused some of them. I did review Jeff Boyd's expert</p> <p>21 report. I can't recall all of them. I think Ie-Ming</p> <p>22 Shih's I perused.</p> <p>23 Q. Okay. You say you did review Shih and Permuth?</p> <p>24 A. Yeah. No, Jeff Boyd's, Dr. Boyd's report. I don't</p> <p>25 recall all of them. I've reviewed and looked through</p>	<p style="text-align: right;">Page 217</p> <p>1 opinions or more opinions, I will need to know about</p> <p>2 that, and we would have to do another deposition if</p> <p>3 that's the case.</p> <p>4 Moving on, did you look at any asbestos</p> <p>5 literature?</p> <p>6 A. As I mentioned previously, I perused the literature on</p> <p>7 asbestos as it pertained to talc, such as the one,</p> <p>8 actually, I think we just reviewed with the Mandarino,</p> <p>9 there was some asb -- but I did not do a deep dive into</p> <p>10 asbestos. If there was asbestos-related research in the</p> <p>11 research I was doing when I was assessing whether talc</p> <p>12 was involved in the pathogenesis of ovarian cancer, I</p> <p>13 did do a critical assessment of asbestos and its role in</p> <p>14 ovarian cancer development initiation.</p> <p>15 Q. Can you direct me to a particular article that you</p> <p>16 reviewed that states that cosmetic talc does not cause</p> <p>17 or contribute to development of ovarian cancer?</p> <p>18 A. Oh, yeah. I think it's the Saed paper, the one that</p> <p>19 he --</p> <p>20 MS. SHARKO: Wait. Listen to the question. I</p> <p>21 think you missed a negative in there. Can you read back</p> <p>22 the question, please?</p> <p>23 BY MS. THOMPSON:</p> <p>24 Q. Can you direct me to any article that you reviewed that</p> <p>25 states that cosmetic talc does not cause or contribute</p>

<p style="text-align: right;">Page 218</p> <p>1 to the development of ovarian cancer?</p> <p>2 A. Oh, sorry. I didn't hear the does not.</p> <p>3 Q. And it's your opinion, correct?</p> <p>4 A. Yeah. Again, I think -- I reviewed a lot of papers and</p> <p>5 there's a lot of epidemiological studies and association</p> <p>6 studies that show that, however, one thing in science,</p> <p>7 very few people publish negative data. And as mentioned</p> <p>8 before, I did not repeat any of these studies because</p> <p>9 there's not enough rationale or conclusive evidence to</p> <p>10 repeat the studies. So the study showing that talc does</p> <p>11 not induce transformation is not published because a lot</p> <p>12 of times, people don't publish that negative data.</p> <p>13 Q. So the answer would be you can't direct me to an article</p> <p>14 that states that for whatever reason, correct?</p> <p>15 A. No.</p> <p>16 MS. THOMPSON: Laura, would you let me know</p> <p>17 when I have five minutes left? I'd like to reserve a</p> <p>18 little time in case Ms. Sharko has questions.</p> <p>19 BY MS. THOMPSON:</p> <p>20 Q. Can you direct me to any article that you reviewed that</p> <p>21 states that genital use of talc is safe?</p> <p>22 A. Again, I think that's several epidemiological studies</p> <p>23 that show no association with ovarian cancer. I can't</p> <p>24 recall off the top of my head what exact studies those</p> <p>25 are.</p>	<p style="text-align: right;">Page 220</p> <p>1 was used in that study.</p> <p>2 Q. And you believe that study, Minerva study, states that</p> <p>3 it's safe to use cosmetic products containing asbestos,</p> <p>4 is that your testimony?</p> <p>5 A. Well, since I don't believe the data and I don't believe</p> <p>6 that it shows that it induces neoplastic transformation.</p> <p>7 Q. So you believe that Saed's work states -- supports your</p> <p>8 opinion that talc is safe?</p> <p>9 A. No, that is not what I said.</p> <p>10 Q. Well, I'm asking for you to direct me to an article that</p> <p>11 states that a cosmetic product that contains asbestos is</p> <p>12 safe. And you're referring me to Saed, correct? Just</p> <p>13 leave it at that.</p> <p>14 A. No. I'm sorry, you mis -- that's not what I said.</p> <p>15 Q. Okay. Well, this is my exact question, so if you'll</p> <p>16 listen to it, because I just have a few more minutes.</p> <p>17 Can you direct me to an article that you reviewed that</p> <p>18 states that a cosmetic product that contains asbestos is</p> <p>19 safe to use on your body?</p> <p>20 A. I am -- I don't -- I have not reviewed the literature</p> <p>21 on -- in that area, so I cannot direct you towards any</p> <p>22 articles that suggest that.</p> <p>23 Q. Can you direct me to an article that states that talc</p> <p>24 particles from the external environment cannot ascend to</p> <p>25 the fallopian tubes, ovaries and peritoneal cavity?</p>
<p style="text-align: right;">Page 219</p> <p>1 Q. But you didn't, as you said, did not do a deep dive into</p> <p>2 epidemiology, correct?</p> <p>3 A. I did not.</p> <p>4 Q. Can you direct me to any article that you reviewed that</p> <p>5 states that there is a safe level of asbestos exposure?</p> <p>6 A. I didn't review the, all the asbestos literature, so I</p> <p>7 cannot direct you to those articles.</p> <p>8 Q. Can you direct me to any article that you reviewed that</p> <p>9 states that a cosmetic product that contains asbestos is</p> <p>10 safe to use?</p> <p>11 A. Again, I guess if I were to repeat myself again, what</p> <p>12 I've done for this report was analyze all of the data</p> <p>13 looking at talc and talc products that could have</p> <p>14 included asbestos, and if I could direct you to an</p> <p>15 article, if the Saed study and Minerva article</p> <p>16 potentially included talc, that study tried to attempt</p> <p>17 to show that it was induced neoplastic transformation,</p> <p>18 and unfortunately, from my expert opinion, did not</p> <p>19 successfully show that talc, and if it did include</p> <p>20 asbestos, was able to induce transformation.</p> <p>21 Q. Well, I'm going to object that. It's nonresponsive,</p> <p>22 because my question was, can you direct me to an article</p> <p>23 that states that a cosmetic product that contains</p> <p>24 asbestos is safe?</p> <p>25 A. The reason I mentioned that one, because cosmetic talc</p>	<p style="text-align: right;">Page 221</p> <p>1 A. I'm going to re -- negative data is never published,</p> <p>2 rarely published, so it's hard to find articles that</p> <p>3 will show that type of work.</p> <p>4 Q. So the answer is no, correct? Can you direct me to any</p> <p>5 article you reviewed that states that talcum powder has</p> <p>6 no biologic effects when found in tissues or added to</p> <p>7 cells in culture?</p> <p>8 A. So if you read many of the discussion for, actually, a</p> <p>9 lot of the papers I reference, many of them allude to</p> <p>10 the fact that they're very descriptive. And the</p> <p>11 biological implications are unclear. So I can't</p> <p>12 pinpoint all of them. But, actually, if you look, they</p> <p>13 actually all state that talc does not have a biological</p> <p>14 effect.</p> <p>15 Q. So your opinion is the articles that we talked about</p> <p>16 today state that talcum powder has no biologic effect?</p> <p>17 A. Yeah.</p> <p>18 Q. So Emi, no biologic effect?</p> <p>19 A. Again, as I mentioned previously, all of those studies</p> <p>20 were descriptive. What I mean by descriptive --</p> <p>21 Q. No. Listen to my question. I don't want --</p> <p>22 MS. SHARKO: No. Don't interrupt the witness.</p> <p>23 Please finish your answer, Dr. DiFeo.</p> <p>24 THE WITNESS: You asked me if it has a</p> <p>25 biological effect. You asked me if it has a biological</p>

<p style="text-align: right;">Page 222</p> <p>1 effect. Biology means that it's a function -- 2 BY MS. THOMPSON: 3 Q. I asked -- 4 A. Sorry. You said biology, right, biological effect? 5 MS. SHARKO: Wait. 6 THE WITNESS: And I was saying, yes, they 7 don't show that there's a biological effect. 8 BY MS. THOMPSON: 9 Q. Do the papers state that there is no biological effect? 10 A. Yes, they do. They actually say that there's no 11 biological effect and additional studies need to show 12 that -- whether there's an effect on immunosurveillance. 13 Actually, I think you read that sentence to me. 14 Q. And that would be true for Emi paper, correct? 15 A. Yeah, I think it was Emi and Mandarino, where they state 16 that further studies needed to be done to show 17 immunosurveillance. 18 Q. Is that initial studies need to be done is saying the 19 same, there's no effect, is that your opinion? 20 A. Yes. Again, highlighting that they're descriptive, RNA 21 levels going up or down, just means that the expression 22 of RNA or genes are going up and down. Whether that 23 results in a biological effect or a functional effect is 24 unknown. They don't know any of that. 25 MS. THOMPSON: Okay. That's all I have.</p>	<p style="text-align: right;">Page 224</p> <p>1 paragraph says, in conclusion -- and again, you were 2 read the first sentence. I'd like to read the rest of 3 the paragraph to you. 4 Moreover, the authors believe that talc may 5 have a stimulating effect on ovaries which should be 6 further investigated, particularly in infertile 7 patients. However, the authors of this study highlight 8 the fact that other environmental factors may have role 9 in the increased follicle number presented by the 10 control group, therefore, separate intensive studies in 11 the series to demonstrate the affect of talc on the 12 ovary should be considered. 13 Did I read that correctly? 14 A. Yes. 15 Q. Have you ever heard of the use of talc as a treatment 16 for infertility? 17 A. No. 18 Q. Okay. You were shown a paper by Smith from 2016 with a 19 proposal for characteristics of carcinogens. That was 20 Exhibit 7. Do you recall that? 21 A. Yes. 22 Q. And you were shown Table 10 that listed ten 23 characteristics. I don't think you need the paper for 24 my question. 25 A. Okay.</p>
<p style="text-align: right;">Page 223</p> <p>1 MS. SHARKO: Okay. 2 THE WITNESS: I have a couple questions. 3 EXAMINATION BY MS. SHARKO: 4 Q. Dr. DiFeo, you were asked some questions about the 5 carcinogenicity of asbestos. Do you recall those 6 questions, generally? 7 A. In general, yes. 8 Q. Okay. Do you agree that asbestos can cause 9 mesothelioma? 10 A. Yes. 11 Q. Does that mean that asbestos causes all forms of cancer? 12 A. No. 13 Q. Okay. Let's go to Exhibit 10. The Keskin paper. On 14 the first page, the Conclusion section, you were read 15 the first sentence of the conclusion. I'd like to read 16 to you the rest of that section. It says, However, this 17 effect is in the form of foreign body reaction and 18 infection rather than being neoplastic. 19 Did I read that correctly? 20 A. Yes. 21 Q. What does neoplastic mean? 22 A. Tumorigenic or -- 23 Q. Causing cancer? 24 A. Causing cancer. 25 Q. Okay. And then on the last page of the paper, the last</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. But if you do, let me know. 2 A. Okay. 3 Q. You were shown Table 10 with ten characteristics. 4 A. Um-hum (affirmatively). 5 Q. You have to say yes or no. 6 A. Yes. Sorry. 7 Q. Do all ten of those apply to ovarian cancer 8 specifically? 9 A. No. 10 Q. If something is not inert, does that mean it's 11 carcinogenic? 12 A. No. 13 Q. Can you give me an example of something that is not 14 inert but is not carcinogenic? 15 A. Something like poison ivy, when you're exposed to it can 16 cause an effect; but, obviously, poison ivy's not 17 carcinogenic or can cause cancer. 18 Q. You've asked whether you've reviewed -- 19 MS. THOMPSON: I'm sorry, I couldn't hear your 20 answer. 21 MS. O'DELL: I could not hear that answer 22 either. 23 THE WITNESS: Oh, sorry. I said something 24 like poison ivy is not inert, it causes a reaction, but 25 it's not carcinogenic, it doesn't cause cancer.</p>

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<p>1 BY MS. SHARKO:</p> <p>2 Q. You were asked whether you've reviewed the IARC</p> <p>3 monographs. Do you recall those questions?</p> <p>4 A. Yes.</p> <p>5 Q. Do you consult IARC monographs in your usual work</p> <p>6 outside of litigation?</p> <p>7 A. No.</p> <p>8 Q. You were asked some questions about whether you followed</p> <p>9 the methodology in a philosophical paper by Dr. Rothman,</p> <p>10 Exhibit 6. Do you remember those questions?</p> <p>11 A. Yes.</p> <p>12 Q. Did you, when you evaluated this case and wrote your</p> <p>13 report, use the same methodology here that you use when</p> <p>14 you're working in your lab?</p> <p>15 A. Yes.</p> <p>16 Q. There were a lot of questions about epidemiology. Did</p> <p>17 you need to take a deep dive into the epidemiological</p> <p>18 literature to answer the question you were asked to</p> <p>19 address in your report?</p> <p>20 A. I did not. That's the reason I didn't include it. I</p> <p>21 think -- the epidemiological studies provide a</p> <p>22 suggestion that talc is associated or potentially</p> <p>23 associated with ovarian cancer, and the goal that I had</p> <p>24 was now to assess whether that association was</p> <p>25 meaningful and whether that -- assess whether talc was</p>	<p>1 CERTIFICATE OF NOTARY</p> <p>2</p> <p>3 STATE OF MICHIGAN)</p> <p>4) SS</p> <p>5 COUNTY OF MACOMB)</p> <p>6</p> <p>7 I, LAURA J. STEENBERGH, Certified Shorthand</p> <p>8 Reporter, a Notary Public in and for the above county</p> <p>9 and state, do hereby certify that the above deposition</p> <p>10 was taken before me at the time and place hereinbefore</p> <p>11 set forth; that the witness was by me first duly sworn</p> <p>12 to testify to the truth, and nothing but the truth, that</p> <p>13 the foregoing questions asked and answers made by the</p> <p>14 witness were duly recorded by me stenographically and</p> <p>15 reduced to computer transcription; that this is a true,</p> <p>16 full and correct transcript of my stenographic notes so</p> <p>17 taken; and that I am not related to, nor of counsel to</p> <p>18 either party nor interested in the event of this cause.</p> <p>19</p> <p>20 <%33,Signature%></p> <p>21</p> <p>22 LAURA J. STEENBERGH</p> <p>23 CSR 3707 Notary Public,</p> <p>24 Macomb County, Michigan</p> <p>25 My Commission expires: 2/14/28</p>
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<p>1 driving the disease. The analogy I commonly use when</p> <p>2 I'm giving a cancer biology lecture every semester is,</p> <p>3 when there's an association made either with a gene, a</p> <p>4 carcinogen, potential carcinogen or factor, we need to</p> <p>5 assess whether it is a passenger on the bus or the</p> <p>6 driver. So I didn't see that it was relevant to include</p> <p>7 any of the epidemiological studies in the report, but</p> <p>8 mainly focus on all of the studies that determine</p> <p>9 whether talc was a driver.</p> <p>10 MS. SHARKO: Those are all my questions.</p> <p>11 Thank you very much.</p> <p>12 Margaret, anything else?</p> <p>13 MS. THOMPSON: I don't believe so. So off the</p> <p>14 record.</p> <p>15 (The deposition was concluded at 6:17 p.m.)</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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